



## PRIOR AUTHORIZATION POLICY

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

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

**REVIEW DATE:** 11/12/2025; selected revision 02/11/2026

### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **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 uses:

- **High-Altitude pulmonary edema (HAPE).** Published guidelines for the prevention and treatment of HAPE recommend nifedipine as the preferred pharmacologic treatment option.<sup>11</sup> Regarding PDE5 inhibitors, tadalafil is given a strong recommendation for HAPE prevention in known susceptible individuals who are not candidates for nifedipine. Dexamethasone is recommended for

prevention if the patient is not a candidate for nifedipine and tadalafil. For HAPE treatment, PDE5 inhibitors may be used if nifedipine is not available.

- **Prophylaxis after radical prostatectomy.** Multiple studies have evaluated the efficacy of tadalafil for prophylaxis after radical prostatectomy.<sup>5-7</sup>
- **Pulmonary arterial hypertension (PAH).** PAH is a serious but rare condition affecting fewer than 20,000 patients in the US.<sup>12,13</sup> It is classified within Group 1 pulmonary hypertension among the five different groups that are recognized by the World Health Organization (WHO). In this progressive disorder, the small arteries in the lungs become narrowed, restricted, or blocked causing the heart to work harder to pump blood, leading to activity impairment. Although the mean age of diagnosis is between 36 and 50 years, patients of any age may be affected, including pediatric patients. PAH is defined as a mean pulmonary artery pressure (mPAP) > 20 mmHg (at rest) with a pulmonary arterial wedge pressure (PAWP) ≤ 15 mmHg and a pulmonary vascular resistance > 2 Wood units measured by cardiac catheterization.<sup>14</sup>

The CHEST guideline and Expert Panel Report regarding therapy for PAH in adults (2019) details many medications. It was noted that PDE5 inhibitors play a vital role and have various benefits in the management of PAH.<sup>13</sup> The European Society of Cardiology and the European Respiratory Society guidelines regarding the treatment of pulmonary hypertension (2022) also recognize PDE5 inhibitors as having a prominent role in the management of this condition, as monotherapy or in use as combination with other agents.<sup>15</sup>

Adcirca<sup>®</sup> (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.

**Documentation:** Documentation is required for initiation of therapy as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and catheterization laboratory reports. All documentation must include patient-specific identifying information. For a patient case in which the documentation requirement of the right heart catheterization upon Prior Authorization coverage review for a different medication indicated for pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1 has been previously provided, the documentation requirement in this *Erectile Dysfunction – Tadalafil Prior Authorization Policy* is considered to be met.

• **Cialis® (tadalafil tablets - Eli Lilly, generic)**  
**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### **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 include finasteride and 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 if the patient meets BOTH of the following (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 or prevention of HAPE are nifedipine, dexamethasone, and sildenafil.

**4. Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year if the patient meets 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 a urologist.

**5. Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].** Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i.** Patient meets BOTH of the following (a and b):
    - a)** Patient has had a right heart catheterization [**documentation required**]; AND
    - b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
  - ii.** The medication is prescribed by or in consultation with a cardiologist or pulmonologist; AND
- B) Patient is Currently Receiving Tadalafil for PAH.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i.** Patient meets BOTH of the following (a and b):
    - a)** Patient has had a right heart catheterization; AND  
Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH.
    - b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
  - ii.** The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

**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 COVERED**

- **Cialis® (tadalafil tablets - Eli Lilly, generic) is(are) considered not medically necessary for ANY other use(s); 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.
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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.
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14. Maron BA. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer. *J Am Heart Assoc.* 2023 Apr 18;12(8):e029024. [Epub].
15. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J.* 2022;43(38):3618-3731.

## HISTORY

| Type of Revision  | Summary of Changes  | Review Date |
|-------------------|---|-------------|
| Annual Revision   | No criteria changes.  | 11/01/2023  |
| Annual Revision   | No criteria changes.  | 11/06/2024  |
| Annual Revision   | No criteria changes.  | 11/12/2025  |
| Selected Revision | <p><b>High-Altitude Pulmonary Edema (HAPE), Treatment or Prevention:</b> Serevent (salmeterol inhalation powder) and acetazolamide were removed as examples of pharmacologic therapy for the treatment or prevention of HAPE.</p> <p><b>Pulmonary Arterial Hypertension (PAH):</b> Added that PAH is World Health Organization (WHO) Group 1. For Initial Therapy and a Patient Currently Receiving Tadalafil for PAH, requirements were added that the patient has had a right heart catheterization (documentation required for Initial Therapy) and the results confirm the diagnosis of WHO Group 1 PAH, and that the medication is prescribed by or in consultation with a cardiologist or a pulmonologist. The requirement that the patient cannot use Adcirca (tadalafil, generic) due to dose availability was removed.</p> | 02/11/2026  |

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