Effective Date **2/1/2025**
Coverage Policy Number **IP0097**

Tadalafil (Cialis®) for Employer Group Plans

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Related Coverage Resources

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 and have discretion in making individual coverage determinations. 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.

Overview

This policy supports medical necessity review for tadalafil (**Cialis**®).

The use of tadalafil (Adcirca®, Alyq™) for pulmonary hypertension is addressed in a separate coverage policy. Please refer to the related coverage policy link above.

Coverage for brand Cialis (tadalafil) varies across plans and may require the use of Step Therapy in accordance with benefit plan specifications. Refer to the customer's benefit plan document for coverage details.

For plans that do NOT include coverage for sexual dysfunction, medical necessity review may be required in addition to the Step Therapy requirements for non-sexual dysfunction uses. Refer to the customer's benefit plan document for coverage details.

Medical Necessity Criteria

Tadalafil (Cialis) is considered medically necessary when the individual meets **ONE** of the following:

1. **Treatment of Erectile Dysfunction.**
   Erectile dysfunction therapy is specifically excluded under many benefit plans [both Employer Groups and Individual and Family Plans]. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage (for example, quantity limitations).

   Tadalafil (Cialis) for Use as Needed for Erectile Dysfunction
   Where covered, a maximum quantity limitation up to 8 tablets per 30 days is allowed of tadalafil (Cialis) 5mg, 10mg, or 20mg.

   Tadalafil (Cialis) for Once Daily Use for Erectile Dysfunction
   Where covered, a maximum quantity limitation of 30 tablets per 30 days is allowed of tadalafil (Cialis) 2.5 or 5mg.

   Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Cialis (tadalafil)	Trial of **tadalafil** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

2. **Treatment Of Benign Prostatic Hyperplasia (BPH).** Individual meets **ALL** of the following criteria:
   A. Documentation of **ONE** of the following:
      i. Dosage of tadalafil used will be 5mg once daily
      ii. Dosage of tadalafil used will be 2.5mg once daily, if significant clinical concern such that the individual is unable to use the 5mg daily dosage (for example, creatinine clearance of 30-50 ml/min or concomitant potent inhibitors of CYP3A4, such as ketoconazole or ritonavir)
   B. Documentation of failure, contraindication, or intolerance to **ONE** of the following:
      i. Alpha1-blocker
      ii. 5 alpha-reductase inhibitor
      iii. 5 alpha-reductase inhibitor/alpha1-blocker combination product

   Tadalafil (Cialis®) for Once Daily Use for Benign Prostatic Hyperplasia
   Where covered, a maximum quantity limitation of 30 tablets per 30 days is allowed of tadalafil (Cialis) 2.5 or 5mg

3. **Treatment Of Raynaud's Phenomenon.** Individual meets the following criteria:
   A. Documentation of failure, contraindication, or intolerance to **ONE** calcium channel blocker

4. **Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Individual meets **ALL** of the following criteria:
   A. Documentation of radical prostatectomy within the previous 12 months
   B. Medication is prescribed by, or in consultation with, an urologist.

5. **Prevention or Treatment of High-Altitude Pulmonary Edema (HAPE).** Individual meets **ALL** of the following criteria:

A. Documented diagnosis of HAPE or history of HAPE
B. Documentation of failure, contraindication, or intolerance to **ONE** other pharmacologic therapy for the treatment or prevention of HAPE

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.
Receipt of sample product does not satisfy any criteria requirements for coverage.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Tadalafil (Cialis) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration:
1. Erectile Dysfunction: up to 12 months
2. Benign Prostatic Hyperplasia: up to 12 months
3. Raynaud's Disease: up to 12 months
4. Prophylaxis After Radical Prostatectomy: not applicable for continuation beyond initial 12 months
5. High-Altitude Pulmonary Edema (HAPE): not applicable for continuation beyond initial 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Background

OVERVIEW
Tadalafil (Cialis, generic), a phosphodiesterase type 5 (PDE5) inhibitor, is indicated for the following uses[1]:

- **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 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.[8-10]

- **Raynaud's phenomenon.** There are studies which show tadalafil has been beneficial in patients with Raynaud's phenomenon.[2,3] 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.[4] Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

References

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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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8. Adcirca tablets [prescribing information]. 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.
11. Luks AM, Auerbach PS, Freer L, et al. Wilderness Medical Society Consensus Guidelines for the Prevention and Treatment of Acute Altitude Illness: 2019 Update. Available at: https://www.wemjournal.org/article/S1080-6032(19)30090-0/fulltext. Accessed on November 4, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	2/1/2025

The policy effective date is in force until updated or retired.