

Tadalafil

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Indication	Medication	Maximum Quantity Limit
Benign prostatic hyperplasia (BPH)	Cialis (2.5mg, 5mg tablets ONLY)	30 tablets per 30 days
Erectile Dysfunction*	Cialis 2.5mg, 5mg, 10mg, 20mg tablets	*Subject benefit and quantity limits specific to member's evidence of cover (EOC)
Pulmonary Arterial Hypertension (PAH)	Adcirca 20mg tablets Alyq 20mg tablets Tadliq Suspension 20mg/5mL	2 tablets per day 2 tablets per day 10 mL per day

*For erectile dysfunction medications, requests are subject benefit and quantity limits specific to member's evidence of cover (EOC). Exceptions to these quantities will be reviewed on a case by case basis. Concomitant use of oral ED medications is NOT a covered benefit. Requests for Cialis in the treatment of Pulmonary Arterial Hypertension will be reviewed on a case by case basis.

APPROVAL CRITERIA

I. **Diagnosis of Erectile Dysfunction:**

- A. Individual has a documented diagnosis of erectile dysfunction**, defined as the consistent inability to achieve and/or maintain an erection sufficient for sexual activity (AUA 2018).

**may include diagnosis of impotence of organic origin

Cialis (tadalafil) for ED **may not** be approved for the following:

I. Use in combination with any of the following:

- A. A guanylate cyclase stimulator [including but not limited to, Adempas (riociguat)]; **OR**
- B. Other PDE5 inhibitor agents [including but not limited to, Adcirca, Revatio]; **OR**
- C. An organic nitrate, including but not limited to, isosorbide mono/dinitrate or nitroglycerin.

II. **Diagnosis of Pulmonary Arterial Hypertension:**

Initial requests:

- A. Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1]¹; **AND**
- B. Individual has the diagnosis of PAH confirmed by a right-heart catheterization showing all of the following (Hoeper, 2013; Ivy, 2013; Abman, 2015):
 1. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest;
 2. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-

- diastolic pressure (LVEDP) less than or equal to 15 mm Hg;
3. Pulmonary vascular resistance (PVR) greater than 3 Wood units; **AND**
- C. Individual has WHO functional class II-III² symptoms.

Continuation requests:

- A. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

Adcirca (tadalafil), Alyq (tadalafil), Tadliq Suspension (tadalafil) **may not** be approved for the following:

- I. Individuals requesting for the treatment of benign prostatic hyperplasia hypertension and/or erectile dysfunction; **OR**
- II. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
- III. Individual has severe renal impairment (creatinine clearance less than or equal to 30 mL/min) or on dialysis; **OR**
- IV. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD); **OR**
- V. Individual has a known hereditary degenerative retinal disorder (including but not limited to, retinitis pigmentosa); **OR**
- VI. Use in combination with guanylate cyclase stimulators [including but not limited to, Adempas (riociguat)]; **OR**
- VII. Use in combination with other phosphodiesterase-5 (PDE-5) inhibitors [including but not limited to, Cialis (tadalafil) or Revatio/Liqrev (sildenafil)]; **OR**
- VIII. Use in combination with organic nitrates, including but not limited to, isosorbide mono/dinitrate or nitroglycerin.

III. Diagnosis of Benign Prostatic Hyperplasia (BPH):

- A. Individual has a diagnosis of benign prostatic hyperplasia (BPH); **AND**
 - B. Individual is using Cialis to treat signs and symptoms of BPH;
- AND**
- C. Individual has had a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to **TWO** preferred agents for BPH:

Preferred/Generic agents for BPH: Alfuzosin (generic Uroxatral), doxazosin (generic Cardura), dutasteride (generic Avodart) (Not covered in CA, CO). finasteride (generic Proscar)^{***}, tamsulosin (Not covered in CA, CO), terazosin, silodosin (generic Rapaflo) (Not covered in CA, CO).

OR

- D. The preferred agents are unacceptable due to concomitant clinical conditions, including but not limited to the following:
 - 1. Individual has a documented hypersensitivity to any ingredient in the preferred agents which is not also in Cialis; **OR**
 - 2. Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred agents and acceptable for use with Cialis.

Cialis (tadalafil) 2.5 mg and 5 mg for BPH **may not** be approved for the following:

- I. Individual is requesting for the treatment of pulmonary arterial hypertension; **OR**
- II. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
- III. Individual has severe renal impairment (creatinine clearance less than 30 mL/min) or on hemodialysis; **OR**
- IV. Individual has a known hereditary degenerative retinal disorder (including but not limited to, retinitis pigmentosa); **OR**
- V. Use in combination with any of the following:
 - A. A guanylate cyclase stimulator [including but not limited to, Adempas (riociguat)]; **OR**
 - B. Other phosphodiesterase 5 (PDE5) inhibitor agents [including but not limited to, Adcirca (tadalafil)]; **OR**
 - C. An organic nitrate, including but not limited to, isosorbide mono/dinitrate or nitroglycerin;

OR

- VI. Individual has any of the following cardiovascular conditions:
 - A. Myocardial infarction within the previous 90 days; **OR**
 - B. Unstable angina or angina occurring during sexual intercourse; **OR**
 - C. Greater than or equal to New York Heart Association (NYHA) Class II heart failure within the previous 6 months; **OR**
 - D. Uncontrolled arrhythmias; **OR**
 - E. Hypotension (less than 90/50 mmHg) or uncontrolled hypertension; **OR**
 - F. Stroke within the previous 6 months.

Notes:

Up to 30 tablets per 30 days is allowable if the criteria for benign prostatic hyperplasia (BPH) are met.

*** If Cialis is being utilized concurrently with Proscar (finasteride) to initiate BPH treatment, treatment with Cialis 5 mg once daily is recommended for up to 26 weeks.

1. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009):
 - A. Group 1: Pulmonary arterial hypertension (PAH)
 - B. Group 2: PH due to left heart disease
 - C. Group 3: PH due to lung diseases and/or hypoxia
 - D. Group 4: Chronic thromboembolic PH (CTEPH)
 - E. Group 5: Miscellaneous/PH with unclear multifactorial mechanisms.
2. WHO functional classification of PH (CHEST 2019):
 - A. Class I: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
 - B. Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
 - C. Class III: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
 - D. Class IV: Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

Key References:

1. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society (AHA/ATS). *Circulation*. 2015; 132(21):2037-2099.
 2. Badesch BD, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131(6):1917-1928.
 3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 10, 2023.
 4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
 5. Hoeper MM, Bogaard HJ, Condliffe R, et al. Definitions and Diagnosis of Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D42- D50. Available at: http://www.onlinejacc.org/content/62/25_Supplement/D42. Accessed: July 10, 2023.
 6. Ivy DD, Abman SH, Barst RJ, et al. Pediatric Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D117- D126. Available from: http://www.onlinejacc.org/content/62/25_Supplement/D117. Accessed: July 10, 2023.
 7. Klinger JR, Elliott CG, Levine DJ, et. al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report. *CHEST*. 2019; 155(3): 565-586.
 8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
 9. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension. A report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association. *J Am Coll Cardiol*. 2009; 53:1573-1619. Available at: <http://circ.ahajournals.org/content/119/16/2250.full.pdf+html>. Accessed: July 10, 2023.
 10. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019; 53(1).
- Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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