

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	NA	NA

Tadalafil

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Comments
Cialis (tadalafil)	Requests for Cialis in the treatment of Pulmonary Arterial Hypertension (PAH) will be reviewed on a case by case basis. ONLY 2.5mg and 5mg strengths for a diagnosis of Benign Prostatic Hyperplasia (BPH).
Adcirca (tadalafil) Alyq (tadalafil)	ONLY for a diagnosis of PAH

APPROVAL CRITERIA

Requests for Adcirca (tadalafil), Alyq (tadalafil) may be approved if the following criteria are met:

- I. Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1]¹; **AND**
- II. Individual has the diagnosis of PAH confirmed by a right-heart catheterization showing all of the following (Hoepfer, 2013; Ivy, 2013; Abman, 2015):
 - A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest;
 - B. 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;
 - C. Pulmonary vascular resistance (PVR) greater than 3 Wood units; **AND**
- III. Individual has WHO functional class II-IV² symptoms.

Requests for Adcirca (tadalafil), Alyq (tadalafil) may not be approved for the following:

- I. Individuals requesting for the treatment of benign prostatic hyperplasia 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 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 (such as but not limited to, retinitis pigmentosa); **OR**

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- VI. Use in combination with guanylate cyclase (GC) stimulators [such as but not limited to, Adempas (riociguat)]; **AND**
- VII. Use in combination with other phosphodiesterase-5 inhibitors (PDE-5) [such as but not limited to, Cialis (Tadalafil)]; **AND**
- VIII. Use in combination with organic nitrates, such as but not limited to, isosorbide mono/dinitrate or nitroglycerin.

Requests for Cialis (tadalafil) 2.5 mg and 5 mg ONLY may be approved if the following criteria are met:

- I. Individual has a diagnosis of benign prostatic hyperplasia (BPH); **AND**
- II. Individual is using to treat the signs and symptoms of BPH; **AND**
- III. Individual has had a previous trial and inadequate response or intolerance to **TWO** preferred agents for BPH;

Preferred agents for BPH: finasteride 5 mg (generic Proscar), doxazosin, tamsulosin, terazosin, alfuzosin.

OR

- IV. The preferred agents are unacceptable due to concomitant clinical conditions, such as but not limited to the following:
 - A. Individual has a documented hypersensitivity to any ingredient in the preferred agents which is not also in Cialis; **OR**
 - B. 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 (such as but not limited to, retinitis pigmentosa); **OR**
- V. Use in combination with any of the following:
 - A. A guanylate cyclase stimulator [such as but not limited to, Adempas (riociguat)]; **OR**
 - B. Other phosphodiesterase 5 (PDE5) inhibitor agents [such as but not limited to, Adcirca (tadalafil)]; **OR**
 - C. An alpha-blocker agent for the treatment of BPH; **OR**
 - D. An organic nitrate, such as but not limited to, isosorbide mono/dinitrate or nitroglycerin;

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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:

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 2014):
 - 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.

3. 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.

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: January 13, 2020.

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Hooper 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: January 17, 2020.
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: January 17, 2020.
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.; 2020; 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: January 15, 2020.
10. McVary KT, Roehrborn CG, Avins AN, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH) Revised 2010. Reviewed and validity confirmed: 2014. Available from: <http://www.auanet.org/education/clinical-practice-guidelines.cfm>. Accessed on: March 11, 2020.

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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