Sildenafil

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

Indication	Medication	Quantity Limit
Erectile Dysfunction**	Sildenafil 25mg, 50mg, 100mg tablets	*Subject to evidence of cover (EOC) allowed quantity
Pulmonary Arterial Hypertension (PAH)	Sildenafil 20mg tablets	3 tablets 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 erectile dysfunction medications is NOT a covered benefit. Requests for sildenafil 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

Sildenafil for erectile dysfunction **may not** be approved for the following:

I. Use in combination with any of the following:
   A. A guanylate cyclase stimulator [such as but not limited to, Adempas (riociguat)]; **OR**
   B. Other PDE5 inhibitor agents [such as but not limited to, Adcirca, Revatio]; **OR**
   C. An organic nitrate, such as but not limited to, isosorbide mono/dinitrate or nitroglycerin.

II. **Diagnosis of Pulmonary Arterial Hypertension for Oral sildenafil:**
Initial requests:

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A. Individual has pulmonary arterial hypertension [PAH) [World Health Organization (WHO Group 1][1]; **AND**
B. Individual has 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-IV[2] symptoms;
    OR
D. Individual has a diagnosis of persistent pulmonary hypertension of the new born (Abman); **AND**
E. Individual was started and stabilized on sildenafil in the hospital and requires continued outpatient therapy;

Continuation requests:

A. There is 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).

Oral sildenafil may **not** be approved for the following:

I. Individual is requesting for the treatment of erectile dysfunction; **OR**
II. Individual has severe hepatic impairment (Child-Pugh Class C); **OR**
III. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD); **OR**
IV. Individual has a known hereditary degenerative retinal disorder (such as but not limited to, retinitis pigmentosa); **OR**
V. Use in combination with guanylate cyclase stimulators [including but not limited to, Adempas (riociguat) or Verquvo (vericiguat)]; **OR**
VI. Use in combination with other phosphodiesterase-5 inhibitors [including but not limited to Adcirca/Alyq/Tadliq (tadalafil) or Viagra (sildenafil)]; **OR**
VII. Individual is on concurrent therapy with organic nitrates, such as but not limited to, isosorbide mono/dinitrate or nitroglycerin.

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):

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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. Conformable 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: January 16, 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: January 16, 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: January 16, 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: January 16, 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).

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