

Commercial/Healthcare Exchange PA Criteria

Effective: 5/11/2018

Prior Authorization: Alyq (tadalafil)

Products Affected: Alyq (tadalafil) 20mg oral tablets

Medication Description:

Tadalafil is an inhibitor of phosphodiesterase type 5 (PDE5), the enzyme responsible for the degradation of cyclic guanosine monophosphate (cGMP). Pulmonary arterial hypertension is associated with impaired release of nitric oxide by the vascular endothelium and consequent reduction of cGMP concentrations in the pulmonary vascular smooth muscle. PDE5 is the predominant phosphodiesterase in the pulmonary vasculature. Inhibition of PDE5 by tadalafil increases the concentrations of cGMP resulting in relaxation of pulmonary vascular smooth muscle cells and vasodilation of the pulmonary vascular bed.

Covered Uses: Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.

Exclusion Criteria:

1. Concomitant use of any form of organic nitrate, either regularly or intermittently
2. Concomitant use of Guanylate Cyclase (GC) Stimulators (eg, riociguat)
3. Known serious hypersensitivity to tadalafil

Required Medical Information:

1. Diagnosis
2. World Health Organization (WHO) functional class
3. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a pulmonologist or a cardiologist

Coverage Duration: 12 months

Other Criteria:

Pulmonary Arterial Hypertension

- A. Patient has clinically documented PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure; **AND**
- B. Patient has tried and failed, or has a contraindication or intolerance to sildenafil 20mg oral tablet.

References:

1. Product Information: ALYQ(TM) oral tablets, tadalafil oral tablets. Teva Pharmaceuticals USA Inc (per manufacturer), North Wales, PA, 2019.
2. Tadalafil. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated April 14, 2020. Accessed June 18, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Updated coverage duration to 12 months Removal of other criteria: Patient must not be using tobacco products. Removal of other criteria: NYHA functional class	All	7/1/2020