

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Phosphodiesterase Type 5 Inhibitors (PDE-5 Inhibitors) for Pulmonary Arterial Hypertension: Adcirca/Alyq (tadalafil), Revatio (sildenafil)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Pulmonary Arterial Hypertension is a rare but serious condition characterized by elevated pulmonary arterial resistance. Adcirca, Alyq and Revatio are phosphodiesterase Type 5 Inhibitors approved for the treatment of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1. Revatio is indicated in adults with PAH to improve exercise ability and delay clinical worsening. Adcirca and Alyq are approved in adults with PAH to improve exercise capacity, measured by improvement in 6-minute walking distance.

Phosphodiesterase Type 5 Inhibitors (PDE-5 Inhibitors) will be considered for coverage when the following criteria are met:

Pulmonary Arterial Hypertension [WHO Group 1]

For **initial** authorization:

1. Member is at least eighteen years of age or older;
2. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
3. Member must have a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization;
4. Member must have documentation PAP pressures are not adequately controlled, confirmed by **one** of the following:
 - a) Patient had an acute response to vasodilator testing AND has tried a calcium channel blocker (CCB) for at least 3 months; OR
 - b) Patient did not have a response to vasodilator testing; OR
 - c) Patient cannot undergo vasodilator testing; OR
 - d) Patient cannot take CCB therapy
5. **Dosage allowed/Quantity limit:**
 Adcirca/Alyq: 40 mg once daily
 Revatio: 20 mg 3 times daily (maximum dose of 80 mg 3 times daily)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

PDE-5 Inhibitors will be reauthorized when chart notes show at least one of the following:

1. Member has documentation of improvement in signs and symptoms of disease as evidenced by at least **one** of the following:
 - a) Stabilization or improvement in functional class symptoms (see Appendix)
 - b) Stabilization or improvement in 6MWD [6-minute walk distance]

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Phosphodiesterase Type 5 Inhibitors (PDE-5 Inhibitors) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/15/2011	Pulmonary Arterial Hypertension policy creation.
05/13/2014	Combined all PAH agents into one policy
07/09/2015	Revised guidelines for therapy aligning with CMS
08/18/2015	Revised guidelines to include diagnosis criteria
10/13/2021	Separated PAH agents by drug class; Updated guidelines; Added provider specialty

References:

1. Revatio [package insert]. New York, NY: Pfizer, Inc; February 2020
2. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2019
3. Alyq [package insert]. New York, NY: Pfizer, Inc; February 2020
4. Coons, J.C., Pogue, K., Kolodziej, A.R. et al. Pulmonary Arterial Hypertension: a Pharmacotherapeutic Update. *Curr Cardiol Rep.* 2019; 21(141)
5. Klinger JR, Elliott CG et al. Therapy for Pulmonary Arterial Hypertension in Adults; *Chest Journal.* March 2019; 155(3): 565-586
6. Galie N, Humbert M, Vachiery JL, Gibbs S, Lang I, Torbicki A, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS): Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). *European heart journal.* 2016;37(1):67–119

Effective date: 04/01/2022

Creation date: 10/13/2021

Appendix:

World Health Organization Functional Assessment Classification	
Class I	Patients with PAH but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea, fatigue, chest pain or near syncope.
Class II	Patients with PAH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity increases dyspnea, fatigue, chest pain, or near syncope.
Class III	Patients with PAH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or near syncope.
Class IV	Patients with PAH unable to carry out any physical activity without symptoms. These patients may have signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.