

PHARMACY POLICY STATEMENT North Carolina 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

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)
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