CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Phosphodiesterase Type 5 Inhibitors (PDE-5 Inhibitors) for Pulmonary Arterial Hypertension: Adcirca/Alyq/Tadliq (tadalafil), Liqrev/Revatio (sildenafil)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Pulmonary Arterial Hypertension is a rare but serious condition characterized by elevated pulmonary arterial resistance. Adcirca, Alyq, Tadliq, Liqrev and Revatio are phosphodiesterase type 5 inhibitors approved for the treatment of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1. Revatio and Liqrev are indicated in adults with PAH to improve exercise ability and delay clinical worsening. Revatio is also indicated in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise. Adcirca, Alyq, and Tadliq are approved in adults with PAH to improve exercise capacity.

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. For Adcirca, Alyq, Tadliq or Liqrev, member is at least 18 years of age or older; AND
2. For Revatio, member is at least 1 year of age or older; AND
3. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
4. Member must have a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization; AND
5. Member has documentation of WHO functional class II, III or IV; AND
6. Member must have documentation of **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;
   b) Patient did not have a response to vasodilator testing;
   c) Patient cannot undergo vasodilator testing;
   d) Patient cannot take CCB therapy.
7. **Dosage allowed/Quantity limit:**
   Adcirca/Alyq/Tadliq: 40 mg orally once daily. Quantity Limit: 60 tablets or 300 mL per 30 days.
   Liqrev: 20 mg orally three times daily. Quantity Limit: 60 mg per day or 6 mL per day.
   Revatio: Quantity Limit: 360 tablets per 30 days or 720 mL per 30 days.
   a) Adults: 20 mg orally 3 times daily (maximum dose of 80 mg orally 3 times daily)
   b) Pediatrics:
      a. ≤20 kg: 10 mg orally three times daily;
      b. 20 kg to 45 kg: 20 mg orally three times daily;
      c. >45 kg: 20 mg orally three times daily (maximum dose of 40 mg orally 3 times daily).

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

For **reauthorization**:

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
03/24/2023	Updated references. Added Tadliq to policy. Added quantity limit. Expanded Revatio age limit.
05/09/2023	Added Liqrev to policy; Added documentation of baseline WHO functional class II, III or IV to align with guidelines.
04/18/2024	Updated references; removed PAH diagnosis from appendix.

Appendix:

World Health Organization Functional Assessment Classification	
Class I	Patients without limitation of physical activity. Ordinary physical activity does not cause undue dyspnea, fatigue, chest pain or near syncope.
Class II	Patients with 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 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 unable to carry out any physical activity without symptoms. These patients may have signs of right-heart failure. Dyspnea and/or fatigue may even by present at rest. Discomfort is increased by any physical activity.

References:

1. Revatio [package insert]. New York, NY: Pfizer, Inc; 2023.
2. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; 2020.
3. Alyq [package insert]. New York, NY: Pfizer, Inc; 2023.
4. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; 2022.
5. Liqrev [package insert]. Farmville, NC: CMP Pharma, Inc.: 2023.
6. Coons, J.C., Pogue, K., Kolodziej, A.R. et al. Pulmonary Arterial Hypertension: a Pharmacotherapeutic Update. *Curr Cardiol Rep.* 2019; 21(141)
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 [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest*. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030

8. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Respir J*. 2023;61(1):2200879. Published 2023 Jan 6. doi:10.1183/13993003.00879-2022
9. Abman SH, Hansmann G, Archer SL, et al. Pediatric Pulmonary Hypertension: Guidelines From the American Heart Association and American Thoracic Society [published correction appears in Circulation. 2016 Jan 26;133(4):e368]. *Circulation*. 2015;132(21):2037-2099. doi:10.1161/CIR.0000000000000329

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