# PDE-5 Inhibitors

**Generic Name:** Phosphodiesterase-5 (PDE-5) Inhibitors

**Therapeutic Class or Brand Name:** PDE-5 Inhibitors

**Applicable Drugs (if Therapeutic Class):** Adcirca (tadalafil), Revatio (sildenafil), Tadliq (tadalafil)

**Preferred:** Sildenafil (generic), tadalafil (generic)

**Non-preferred:** Adcirca (tadalafil), Tadliq (tadalafil), Revatio (sildenafil)

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 11/3/2023

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of Pulmonary Arterial Hypertension (PAH) AND meets criteria A through C:
   A. Classification of World Health Organization (WHO) PAH Group I. Refer to Table 1 in Appendix.
   B. Documentation of right heart catheterization demonstrating 1 through 3:
      1. Mean pulmonary artery pressure (mPAP) ≥ 20 mmHg.
      2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg.
      3. Pulmonary vascular resistance (PVR) > 2 Wood units.
   C. WHO functional class II – IV symptoms. Refer to Table 2 in Appendix.

II. The medication is prescribed by or in consultation with a cardiologist or pulmonologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

## EXCLUSION CRITERIA

- Concurrent use of organic nitrates in any form, either regularly or intermittently.
- Concurrent use of a guanylate cyclase (GC) stimulator (ie, Adempas® (riociguat)).

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adcirca: 60 tablets per 30 days.
- Revatio: 90 tablets per 30 days.

- Sildenafil (generic): 90 tablets per 30 days.
- Tadalafil (generic): 60 tablets per 30 days.
- Tadliq: two 150 ml bottles per 30 days

## APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective.

## APPENDIX

**Table 1. WHO Classification of Pulmonary Hypertension – Group 1**

| | |
|---|---|
| 1.1 | Idiopathic PAH |
| 1.2 | Heritable PAH |
| 1.3 | Drug- and toxin-induced PAH (eg, anorexic agents, cocaine, methamphetamine, L-tryptophan) |
| 1.4 | PAH associated with:*<br>• Connective tissue disorder (eg, Raynaud disease, rheumatoid arthritis, systemic lupus erythematosus, scleroderma)<br>• Portal hypertension<br>• HIV infection<br>• Congenital heart disease with systemic-to-pulmonary shunts (eg, congenital heart disease, including atrial or ventricular septal defect, patent ductus arteriosus, patent foramen ovale, truncus arteriosus, Eisenmenger syndrome, tetralogy of Fallot)<br>• Schistosomiasis |
| 1.5 | PAH long-term responders to calcium channel blockers |
| 1.6 | Pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis |
| 1.7 | Persistent pulmonary hypertension of the newborn |

* Diagnoses, include, but are not limited to these common diagnoses.

**Table 2. WHO Functional Classification of Patients With PAH**

| Class | Symptoms |
|---|---|
| I | No resulting limitation of physical activity. |
| II | slight limitation of physical activity. Comfortable at rest, but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope. |
| III | Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope |
| IV | All physical activity causes symptoms. Signs of right-sided heart failure are present. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity. |

## REFERENCES

1. Adcirca™ [Package Insert], Indianapolis, IN; Eli Lilly and Company; 2020. http://pi.lilly.com/us/adcirca-pi.pdf
2. Revatio™ [Package Insert], Ny, Ny; Pfizer Labs; 2023. http://labeling.pfizer.com/ShowLabeling.aspx?id=645
3. Tadliq™ [Package Insert], Farmville, NC ; CMP Pharma, Inc. ; 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214522s000lbl.pdf
4. 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
5. 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
6. Rajagopal S, et al. American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation, and the Council on Cardiovascular and Stroke Nursing. Evaluation and Management of Pulmonary Hypertension in Noncardiac Surgery: A Scientific Statement From the American Heart Association. *Circulation.* 2023 Apr 25;147(17):1317-1343