

Prior Authorization DRUG Guidelines

ADCIRCA (tadalafil)

Effective Date: 4/22/14 Date Developed: 4/9/14 Date Updated: 10/14/14

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

ADCIRCA is a selective inhibitor of cyclic guanosine monophosphate (cGMP)—specific phosphodiesterase type 5 (PDE5) which facilitates release of nitric oxide and subsequent decrease in vascular smooth muscle tone

Authorization Criteria: Pulmonary arterial hypertension (i.e. average pressure in the pulmonary arteries 25 mmHg or higher)

NOTE: Sometimes used in renal or hepatic impairment; refer to product literature

Dosing: 40 mg once daily

How Supplied: Tablets 20 mg (Cialis: 2.5, 5, 10, 20 mg)

Contraindications/Warnings: Contraindicated if patient is using any form of organic nitrate; use with caution in patients with intrinsic myocardial or valvular problems; use with caution in patients taking medications that affect CYP3A; if priapism occurs, be evaluated within 4-6 hours; use caution with other medications which can cause hypotension or myocardial depression

Major Adverse Reactions: Profound hypotension if used within 24 hours of nitroglycerine or other PDE5 inhibitor use e.g. Viagra (or vice versa); sudden visual loss: non-arteritic anterior ischemic optic neuropathy (NAION); use with caution, or not at all, in patients with known hereditary degenerative retinal disorders; sudden hearing impairment; priapism;

Major Drug Interactions: Nitroglycerine and other PDE5 inhibitors (see above); other medications which may cause hypotension and/or bradycardia



REFERENCES:

- McLaughlin VV, Archer SL, Badesch DB, et al, "ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension: A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association Developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association," J Am Coll Cardiol, 2009, 53(17):1573–619.
- 2. Kloner RA, Mitchell M, and Emmick JT, "Cardiovascular Effects of Tadalafil," *Am J Cardiol*, 2003, 92(9A):37M-46M.
- 3. Ghofrani HA, Voswinckel R, Reichenberger F, et al, "Differences in Hemodynamic and Oxygenation Responses to Three Different Phosphodiesterase-5 Inhibitors in Patients with Pulmonary Arterial Hypertension," *J Am Coll Cardiol*, 2004, 44(7):1488-96.
- 4. Galie N, Brundage BH, Ghofrani HA, et al, "Tadalafil Therapy for Pulmonary Arterial Hypertension," *Circulation*, 2009, 119(22):2894-903.
- 5. Daugan A, Grondin P, Ruault C, et al, "The Discovery of Tadalafil: A Novel and Highly Selective PDE-5 Inhibitor. 2: 2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-b]indole-1,4-dione Analogues," *J Med Chem*, 2003, 46(21):4533-42.
- 6. Curran M and Keating G, "Tadalafil," Drugs, 2003, 63(20):2203-12; discussion 2213-4.
- 7. Adcirca (tadalafil) [prescribing informationt]. Indianapolis, IN: Eli Lilly and Company; April 2014.
- 8. <u>www.uptodate.com</u>: tadalafil: Drug Guidelines

Revision History:

Date Approved by P&T Committee: 4/22/14, 10/28/14; QAC: 5/27/14, 11/25/14

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/Updated: 5/6/15 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

| Revision Date | Content Revised (Yes/No) | Contributors | Review/Revision Notes |
|------------------|--------------------------------|--|--------------------------|
| 1/24/17 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 1/23/18 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |



| 1/22/19 | No | Catherine Sanders, MD; Robert Sterling, MD | Archived – check |
|---------|----|--|------------------|
| | | | ESI |
| | | | |