

# Pharmacy Policy Bulletin

**Title:** Tadalafil (Adcirca™)

**Policy #:** Rx.01.85

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

#### ▶ Intent:

Tadalafil (Adcirca™) is a phosphodiesterase type 5 inhibitor indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability.

The use of tadalafil (Adcirca™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

#### ▶ Description:

Tadalafil (Adcirca™) is an inhibitor of PDE5, the enzyme responsible for the degradation of cGMP. PAH is associated with impaired release of nitric oxide by the vascular endothelium and consequent reduction of cGMP concentrations in the pulmonary vascular smooth muscle. PDE5 is the predominant phosphodiesterase in the pulmonary vasculature. Inhibition of PDE5 by tadalafil increases the concentrations of cGMP resulting in relaxation of pulmonary vascular smooth muscle cells and vasodilation of the pulmonary vascular bed.

#### ▶ Policy:

Tadalafil (Adcirca™) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of pulmonary arterial hypertension
- No documentation or history of nitrate use within the past six months

#### ▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## BENEFIT APPLICATION


Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

#### ▶ References:

Product Information: ADCIRCA (TM) oral tablets, tadalafil oral tablets. Eli Lilly and Company, Indianapolis, IN, 2009.

Galie N, Brundage BH, Ghofrani HA, et al: Tadalafil therapy for pulmonary arterial hypertension. Circulation 2009; Epub:Epub-

#### ▶ Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Adcirca	Tadalafil

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 **Cross References:**

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**Policy Version Number:** 1.00  
**P&T Approval Date:** November 10, 2011  
**Policy Effective Date:** February 01, 2012  
**Next Required Review Date:** November 10, 2012

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