

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> Pulmonary Arterial Hypertension, primary or secondary etiology <input type="checkbox"/> WHO Group I <input type="checkbox"/> NYHA Functional Class II-III symptoms	<input type="checkbox"/> Other (please state): _____ _____ _____
Physician Specialty	<input type="checkbox"/> Pulmonology <input type="checkbox"/> Cardiology	<input type="checkbox"/> Other (please state): _____ _____
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Adcirca <sup>®</sup> (tadalafil )	
	Strength _____ Sig _____ Qty _____ Refills _____	
*Please attach all relevant medical records and test results* <b>Incomplete forms will not be processed.</b>		

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge (please sign and date).**

\_\_\_\_\_  
Prescriber Signature Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician Initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

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## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Adcirca (tadalafil)

#### CLASSIFICATION

- Antihypertensive, Peripheral Vasodilator
- Phosphodiesterase Type 5 Inhibitor (PDE5)

#### DESCRIPTION

- Adcirca is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability. Efficacy was established in studies that included predominately patients with NYHA Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
- In a 16 week, randomized, double-blind, placebo-controlled study (n=405), treatment with tadalafil 40 mg once daily significantly improved the mean 6-minute walk distance in patients with pulmonary arterial hypertension compared to placebo.
- Tadalafil inhibits phosphodiesterase type 5, the predominant phosphodiesterase in the pulmonary vasculature, which is responsible for the degradation of cGMP. 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.
- Monitoring parameters include: Improvement in signs and symptoms of pulmonary arterial hypertension (dyspnea or fatigue, chest pain, or near syncope), exercise capacity, and WHO functional classification, and a decrease in the rate of clinical worsening are indicative of efficacy.
- Due to the complicated nature and severity of PAH as a disease state as well as the high cost of the agents used for PAH, patients should be managed by a pulmonary specialist. Consideration will be given to cardiology specialists.

#### FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

#### COVERAGE CRITERIA

Adcirca (tadalafil) meets the definition of **medical necessity** for the following:

- Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening.
  - NYHA Functional Class II-III symptoms
- Safety and efficacy has not been established in pediatric patients less than 18 years old.

Adcirca (tadalafil) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Pulmonary and Cardiology specialists.

## DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- Pulmonary hypertension: 40 mg ORALLY once daily with or without food

Dose adjustments in PAH:

- Renal impairment:
  - Mild to moderate (CrCl 31 to 80 mL/min): start dosing at 20 mg orally once daily and titrate dose to 40 mg once daily based on tolerability renal impairment
  - Severe (CrCl less than 30 mL/min or on hemodialysis): avoid use
- Hepatic impairment:
  - Mild to moderate, (Child-Pugh Class A or B): start dosing at 20 mg orally once daily
  - Severe (Child-Pugh Class C): avoid use
- Concomitant ritonavir:
  - If on ritonavir for at least one week, start tadalafil 20 mg orally once daily and titrate dose to 40 mg once daily based on tolerability
  - If initiating ritonavir and on tadalafil, stop tadalafil at least 24 hours before starting ritonavir, then resume tadalafil at 20 mg once daily at least 1 week after ritonavir therapy
- Avoid use with concomitant strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole)

## PRECAUTIONS:

- Contraindications
  - Concurrent regular or intermittent use of organic nitrates in any form; hypotensive effects may be potentiated
  - Hypersensitivity to tadalafil or any of its components; Stevens-Johnson syndrome and exfoliative dermatitis have been reported
- Precautions
  - Refer to prescribing information for all precautions
  - Concomitant use with potent CYP3A inhibitors (e.g. ketoconazole, itraconazole) or inducers (e.g. rifampin); avoid use
  - Concomitant use with other phosphodiesterase type 5 (PDE5) inhibitors or erectile dysfunction therapies is not recommended
  - Pulmonary veno-occlusive disease (PVOD); use is not recommended due to potential worsening of cardiovascular status.

## Billing/Coding information

### CPT Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified
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### HCPCS Coding:

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### ICD-9 Diagnoses Codes That Support Medical Necessity:

416.0	Primary pulmonary hypertension

## COST

- AWP (November 2011):
  - Adcirca 20mg tablets (60): \$1,468.80

## COMMITTEE APPROVAL:

- September 2009

## GUIDELINE UPDATE INFORMATION:

September 2009	Prior authorization created
November 2011	Coverage Policy created

## REFERENCES:

- DRUGDEX®, accessed, 11/18/2011
- Product Information: Adcirca® (tadalafil) oral tablets. Pfizer Labs, New York, NY, 2009.