ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Adcirca (tadalafil) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Adcirca (tadalafil)

Diagnosis (documentation supportive of diagnosis is required)

☐ Pulmonary Arterial Hypertension (PAH)
☐ WHO Group I
☐ NYHA Functional Class II to III symptoms
☐ Other (please state): _____

Physician Specialty:

☐ Pulmonology
☐ Cardiology
☐ Other (please state): _____

	☐ For use in clinical trial? (If yes, provide trial name and registration number):		
	Drug Name (Brand Name and Scientific Name)/Strength:		
	Dose:	Route:	Frequency:
	Quantity:	Number of Refills:	
	Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:
	Prescriber or Authorized Signature:		Date:
	Dispensing Pharmacy Name and Phone Number:		
	☐ **Approved**	☐ **Denied**	
	If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:		

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

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 all FDA-approved indications, not otherwise excluded from Part D, including 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

HCPCS Coding:

ICD-9 Diagnoses Codes That Support Medical Necessity:

416.0	Primary pulmonary hypertension

COST

- AWP (November 2011): Adcirca 20mg tablets (60): $1,468.80
- AWP (May 2015): Adcirca 20mg tablets (60): $3,002.40

COMMITTEE APPROVAL:

- September 2009

GUIDELINE UPDATE INFORMATION:

September 2009	Prior authorization created
November 2011	Coverage Policy created
May 2015	Coverage policy reviewed; AWP updated

REFERENCES:

- DRUGDEX®, accessed, 11/18/2011, 05/22/15
- Product Information: Adcirca® (tadalafil) oral tablets. Pfizer Labs, New York, NY, 2015.