

**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): _____ _____
Dosage form	<p><i>For the injectable formulation to be approved, clinical rationale must be given as to why an oral PDE5 inhibitor formulation is inappropriate.</i></p> <input type="checkbox"/> Oral tablets <input type="checkbox"/> Injection (please state rationale): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):  Please attach a copy of the prescription or provide ALL of the information below: Revatio® (sildenafil ) Strength _____ Sig _____ Qty _____ Refills _____	
	<p><i>*Please attach all relevant medical records and test results*</i></p> <p><b>We will not process incomplete forms.</b>  <b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b></p>	

STEP  
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.  
(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

### Revatio (sildenafil)

#### CLASSIFICATION

- Antihypertensive, Peripheral Vasodilator
- Phosphodiesterase Type 5 Inhibitor

#### DESCRIPTION

- Revatio is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening. The delayed clinical worsening was shown in patients stabilized on intravenous epoprostenol in a randomized, double-blind, placebo-controlled clinical study (n=267).
- 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.
- Revatio is given three times daily, either as oral tablets or as an injection (given as an IV bolus). The cost of the injection is about six times that of the oral formulation, despite no additional relative benefit.
- 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.
- Sildenafil citrate is an inhibitor of cGMP specific phosphodiesterase type-5 (PDE5) in smooth muscle, where PDE5 is responsible for degradation of cGMP. Sildenafil citrate increases cGMP within vascular smooth muscle cells resulting in relaxation and vasodilation. In patients with pulmonary hypertension, this leads to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilation in the systemic circulation. In patients with erectile dysfunction, sildenafil citrate enhances the effect of nitric oxide (NO) by inhibiting PDE5 in the corpus cavernosum. When sexual stimulation causes local release of NO, inhibition of PDE5 by sildenafil citrate causes increased levels of cGMP resulting in smooth muscle relaxation and inflow of blood to the corpus cavernosum.
- Sildenafil is a phosphodiesterase inhibitor that was originally developed to treat angina pectoris. It was found to have little effectiveness in a phase I trial; however, male subjects reported erections as an adverse effect, leading to its study as a potential agent for the treatment of impotence.

#### FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T4 (oral); T6 (injection)
Commercial Formulary:	T4 (oral); T6 (injection)
Medicare Part D coverage:	T5 (oral); Part B (injection) if incident to a physician's service

## COVERAGE CRITERIA

Revatio (sildenafil) 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
  - Though not FDA approved in the pediatric population, approval may be considered when clinically necessary
- In order for the injection to be approved versus the oral tablets. A clinical rationale must be given as to why the oral formulation would be less effective or otherwise harmful to the patient. This is due to the significant cost difference between these two formulations.

Revatio (sildenafil) is considered **experimental** for the following:

- Achalasia, primary or secondary sexual/erectile dysfunction, in-vitro fertilization, Raynaud's phenomenon, or any other condition not FDA-approved

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: 20 mg ORALLY 3 times daily; give doses approximately 4 to 6 hr apart
- Pulmonary hypertension: 10 mg IV bolus injection 3 times daily

Dose adjustments

- Liver disease (in PAH): no adjustments needed (Child-Pugh class A and B)
- Renal impairment (in PAH): no adjustments needed

## PRECAUTIONS:

- Contraindications
  - Concurrent regular or intermittent use of organic nitrates in any form; hypotensive effects may be potentiated
  - Concomitant use of HIV protease inhibitors (when used for pulmonary arterial hypertension)
  - Hypersensitivity to sildenafil or any of its components
- Precautions
  - Refer to prescribing information

## Billing/Coding information

### CPT Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified
J3490	Unclassified drugs (Inj solution)

### HCPCS Coding:

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

416.0	Primary pulmonary hypertension

## COST

- AWP (August 2010):
  - Revatio 20mg tablets (90): \$1,544.40
  - Revatio 10mg/12.5ml vial for injection (90): \$10,080.00
- AWP (November 2011):
  - Revatio 20mg tablets (90): \$1,702.80
  - Revatio 10mg/12.5ml vial for injection (90): \$11,115.00

## COMMITTEE APPROVAL:

- August 18, 2010

## GUIDELINE UPDATE INFORMATION:

August 2010	Medical Policy created
November 2011	Medical Policy updated

## REFERENCES:

- DRUGDEX®, accessed 08/09/2010, 11/18/2011
- Product Information: REVATIO(R) oral tablets, IV injection, sildenafil oral tablets, IV injection. Pfizer Labs, New York, NY, 2009.