



**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**

<input type="checkbox"/> <b>Urgent<sup>1</sup></b>		<input type="checkbox"/> <b>Non-Urgent</b>	
<b>Requested Drug Name: Revatio® (sildenafil) IV Only</b>			
<b>Patient Information:</b>		<b>Prescribing Provider Information:</b>	
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:	
<b>Prior Authorization Request for Drug Benefit:</b>		<input type="checkbox"/> New Request <input type="checkbox"/> Reauthorization	
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:			
<p><b>Revatio® (sildenafil) IV Only</b></p> <p><b>Diagnosis (documentation supportive of diagnosis is required)</b></p> <p><input type="checkbox"/> Pulmonary Arterial Hypertension (WHO Group I) and NYHA Functional Class II-III symptoms</p> <p><input type="checkbox"/> Other (please state): _____</p> <p><b>Clinical Consideration</b></p> <p><input type="checkbox"/> For the injectable formulation to be approved, clinical rationale must be given as to why an <u>oral</u> PDE5 inhibitor formulation is inappropriate. <i>(Please state rationale and provide supporting documents from patient's medical record):</i></p> <p>_____</p> <p><b>Note: Oral sildenafil tablets do not require prior authorization</b></p>			



## 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

- 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.
- Revatio is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in adults 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).
- Studies establishing effectiveness were short-term (12 to 16 weeks) and included predominately patients with NYHA Functional Class II-III symptoms. Etiologies were idiopathic (71%) or associated with connective tissue disease (25%).
- Limitation of use: Adding Revatio to Tracleer® (bosentan) therapy does NOT result in any beneficial effect on exercise capacity.
- 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 226 times greater than that of the generic oral formulation, despite no additional relative benefit.

#### FORMULARY COVERAGE

Prior authorization:	Required for IV formulation
Good Health Formulary:	Tier 6
Commercial Formulary:	Tier 6
Medicare Part D coverage:	Tier 5; Part B 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
- In order for the injection to be approved, 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:

- Any condition or diagnosis not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Pulmonary and Cardiology specialists.

## DOSAGE/ADMINISTRATION:

Adult Dosing:

- Usual IV dose for PAH: 2.5 or 10 mg IV bolus injection 3 times daily for continued treatment of pulmonary arterial hypertension in patients who are currently on oral sildenafil but are unable to take oral medication.
- 10-mg IV dose equivalent to 20-mg oral dose.
- Adjustment for body weight not necessary.

Pediatric Dosing:

- Increased mortality with increasing dose was observed in 1 trial with sildenafil (Revatio®) therapy in pediatric pulmonary hypertension patients; therefore, Revatio® therapy, especially chronic treatment, is not recommended in children.

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 or elvitegravir/cobicistat/tenofovir/emtricitabine (when sildenafil is used for PAH).
- Hypersensitivity to sildenafil or any of its components.

### Precautions

- Pediatric patients with pulmonary arterial hypertension; use not recommended due to lack of efficacy of low-dose sildenafil and an increased risk of mortality for high- vs low-dose therapy.
- Pulmonary hypertension secondary to sickle cell disease: Revatio may cause serious vaso-occlusive crises.

- Cardiac failure or coronary artery disease causing unstable angina
- Concurrent use with other phosphodiesterase 5 inhibitors is not recommended.
- Concomitant use with strong CYP3A inhibitors is not recommended (Revatio®).
- Conditions adversely affected by vasodilatory effects (e.g., resting hypotension, fluid depletion, severe left ventricular outflow obstruction, or autonomic dysfunction) may be potentiated.
- Hypertension (blood pressure greater than 170/110 mmHg) or resting hypotension (blood pressure less than 90/50 mmHg).
- Vasodilation effects may be more common in patients with hypotension or on antihypertensive therapy.
- Hearing or visual impairment: Seek medical attention if sudden decrease or loss of vision or hearing occurs.
- Myocardial infarction, stroke, or life-threatening arrhythmia within the last 6 months.
- Non-arteritic anterior ischemic optic neuropathy has been reported during postmarketing use.
- Use of pulmonary vasodilators in pulmonary veno-occlusive disease may significantly worsen cardiovascular status. Use is not recommended.
- Retinitis pigmentosa: genetic disorders of retinal phosphodiesterases may be present.

## Billing/Coding information

### CPT Coding:

J3490	Unclassified drugs (Inj solution)

## COST

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- AWP (August 2010):
  - Revatio 20mg tablets (90): \$1,544.40
  - Revatio 10mg/12.5ml single use vial for IV injection (90): \$10,080.00
- AWP (November 2011):
  - Revatio 20mg tablets (90): \$1,702.80
  - Revatio 10mg/12.5ml single use vial for IV injection (90): \$11,115.00
- AWP (January 2014):
  - sildenafil 20mg tablets (90): ~\$70
  - Revatio 10mg/12.5ml single use vial for IV injection (90): \$15,829.20
- AWP (July 2014):
  - sildenafil 20mg tablets (90): ~\$70
  - Revatio 10mg/12.5ml single use vial for IV injection (90): \$17,089

## COMMITTEE APPROVAL:

- August 18, 2010

## GUIDELINE UPDATE INFORMATION:

August 2010	Medical Policy created
November 2011	Medical Policy updated
May 2014	Medical Policy updated
July 2014	Medical Policy updated

## REFERENCES:

- DRUGDEX®, accessed 08/09/2010, 11/18/2011, 5/14/2014, 7/12/2014
- Product Information: REVATIO® (sildenafil), injection for intravenous use. Pfizer Labs, New York, NY, 2009, 2014.