

Commercial/Healthcare Exchange PA Criteria
Effective: 5/11/2018

Prior Authorization: Revatio (sildenafil)

Products Affected: Revatio (sildenafil) oral tablets, Revatio (sildenafil) oral solution 10mg/ml, Revatio (sildenafil) intravenous solution 10mg/12.5ml, sildenafil oral tablets, sildenafil oral suspension 10mg/ml, sildenafil intravenous solution

Medication 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.

Covered Uses: Treatment of pulmonary arterial hypertension (WHO Group I) in adults to improve exercise ability and delay clinical worsening.

Exclusion Criteria:

1. Concomitant use of organic nitrates in any form, either regularly or intermittently
2. Concomitant use of riociguat, a guanylate cyclase stimulator. PDE-5 inhibitors, including sildenafil
3. Known hypersensitivity to sildenafil

Required Medical Information:

1. Diagnosis
2. World Health Organization (WHO) functional class
3. Current medication regimen

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a pulmonologist or a cardiologist

Coverage Duration: 12 months

Other Criteria:

Pulmonary Arterial Hypertension

- A. Patient has clinically documented PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure).

References:

1. Product Information: REVATIO(R) oral tablets, oral suspension, intravenous injection, sildenafil oral tablets, oral suspension, intravenous injection. Pfizer Labs (per FDA), New York, NY, 2014.
2. Sildenafil. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated May 6, 2020. Accessed June 18, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Removal of other criteria: Patient must not be using tobacco products. Removal of other criteria: NYHA functional class	All	7/1/2020