

Pharmacy Policy Bulletin

Title: Sildenafil (Revatio®)

Policy #: Rx.01.83

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

Sildenafil (Revatio®) is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to improve exercise ability.

The use of sildenafil (Revatio®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

▶ Description:

Sildenafil (Revatio®) is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase-5 (PDE5) in the smooth muscle of the pulmonary arteries, where cGMP is degraded by PDE5. As a result, sildenafil (Revatio®) increases cGMP within the pulmonary arteries, causing relaxation and vasodilation of the pulmonary arteries.

▶ Policy:

Sildenafil (Revatio®) is approved when **all** of the following inclusion criteria are met:

- Documentation of a diagnosis of pulmonary arterial hypertension
- No history of a nitrate prescription being filled within the last six months

▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ References:

Bigatello LM, Hess D, Dennehy KC, et al: Sildenafil can increase the response to inhaled nitric oxide (case report). *Anesthesiology* 2000; 92:1827-1829.

Ghofrani HA, Wiedemann R, Rose F, et al: Combination therapy with oral sildenafil and inhaled iloprost for severe pulmonary hypertension. *Ann Intern Med* 2002; 136(7):515-522.

Jackson G & Chambers J: Sildenafil for primary pulmonary hypertension: short and long-term symptomatic benefit. *Int J Clin Pract* 2002; 56(5):397-398.

Mourani PM, Sontag MK, Ivy DD, et al: Effects of Long-Term Sildenafil Treatment for Pulmonary Hypertension in Infants with Chronic Lung Disease. J Pediatr 2008; Epub:epub-epub.

Pfizer, Inc. FDA approves Pfizer's Revatio® as treatment for pulmonary arterial hypertension. [Pfizer Web site]. Available at: http://www.pfizer.com/news/press_releases/pfizer_press_release_archive.jsp. Accessed December 30, 2011.

Revatio® [package insert]. New York, NY: Pfizer, Inc.; 2009. Also available online at: http://www.pfizer.com/files/products/uspi_revatio.pdf. Accessed December 30, 2011.


Sastry BKS , Narasimhan C , Reddy NK , et al: Clinical efficacy of sildenafil in primary pulmonary hypertension: a randomized, placebo-controlled, double-blind, crossover study. J Am Coll Cardiol 2004; 43(7):1149-1153.

Stiebellehner L, Petkov V, Vonbank K, et al: Long-term treatment with oral sildenafil in addition to continuous IV epoprostenol in patients with pulmonary arterial hypertension. Chest 2003; 123(4):1293-1295.

Watanabe H, Ohashi K, Takeuchi K, et al: Sildenafil for primary and secondary pulmonary hypertension. Clin Pharmacol Ther 2002; 71:398-402.

Zimmermann AT, Calvert AF, & Veitch EM: Sildenafil improves right-ventricular parameters and quality of life in primary pulmonary hypertension (letter). Intern Med J 2002; 32:421-429.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Revatio	sildenafil

Cross References:

Policy Version Number: 1.00
P&T Approval Date: November 10, 2011
Policy Effective Date: February 01, 2012
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