

Policies Repository



Policy Title Sildenafil (Revatio®)

Policy Number FS.CLIN.1

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy Sildenafil (Revatio®) is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to improve exercise ability. There are two types of pulmonary arterial hypertension. Primary pulmonary arterial hypertension (PPAH) is inherited or occurs for no known reason. Secondary pulmonary arterial hypertension (SPAH) occurs as a result of conditions such as chronic heart or lung disease, blood clots in the lungs, or scleroderma.

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

Policy Description Pulmonary arterial hypertension (PAH) is an elevation of pressure in the pulmonary artery. The pulmonary artery carries oxygen-poor blood from the right ventricle in the heart to the small arteries in the lungs. In PAH, the blood vessels can thicken or become blocked by tiny blood clots that narrow the arteries and cause the right side of the heart to work harder to pump blood through the lungs. Over time, the heart muscle weakens and loses its ability to pump enough blood for the body, causing right heart failure. The average blood pressure in a normal pulmonary artery is about 14 mm Hg at rest. In PAH, the average is usually greater than 25 mm Hg at rest and over 30 mm Hg during exercise. These pressures gradually increase as the disease progresses, and many individuals eventually develop resting pulmonary pressures above 100 mm Hg.

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. Individuals treated with sildenafil (Revatio®) have improved physical functioning

as evidenced by increased walking distances, reduced blood pressure in the pulmonary arteries, and increased cardiac outputs.

Policy Guideline Inclusion

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

Policy Guideline Exclusion

Sildenafil (Revatio®) is denied when any of the following exclusion criteria are present:

- Documentation of a diagnosis other than pulmonary arterial hypertension
- A history of a nitrate prescription being filled within the last six months

Policy List of Applicable Drugs

Brand Name	Generic Name
Revatio	Sildenafil

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

McNamara TC. Written communication regarding prior authorization criteria; July 2001.

Pfizer, Inc. FDA approves Pfizer's Revatio® as treatment for pulmonary arterial hypertension. [Pfizer Web site]. 06/06/05. Available at: http://www.pfizer.com/news/press_releases/pfizer_press_release_archive.jsp. Accessed September 13, 2007.

Revatio® [package insert]. New York, NY: Pfizer, Inc.; 2007. Also available online at: http://www.pfizer.com/files/products/uspi_revatio.pdf. Accessed November 14, 2007.

Policy Link to Related Policies

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