

Revatio® (sildenafil) Injection

When requesting Revatio® (sildenafil) injection, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Revatio injection is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease.

Coverage Guidelines

Pulmonary Arterial Hypertension

An individual must meet ALL of the followings:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization
- Is unable to take an oral phosphodiesterase 5 inhibitor (e.g., Revatio [sildenafil tablets or suspension], Adcirca [tadalafil tablets])
- Revatio injection is prescribed by or in consultation with a pulmonologist or a cardiologist

Duration of Approval: 12 months

Dosing Recommendation

The recommended dose is 2.5 mg or 10 mg administered as an intravenous bolus injection three times a day.

References

1. Revatio® tablets, oral suspension, and injection [prescribing information]. New York, NY: Pfizer; January 2019.
2. McGoon M, Gutterman D, Steen V, et al. Screening, early detection, and diagnosis of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. *CHEST*. 2004;126:14-34.
3. McLaughlin VV, Archer SL, Badesch DB, et al; Writing committee members. ACCF/AHA 2009 Expert consensus document on pulmonary hypertension: A report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: Developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. *Circulation*. 2009;119:2250-2294.
4. Badesch, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension. Updated ACCP Evidence-based clinical practice guidelines. *CHEST*. 2007;131:1917-1928.
5. Simonneau G, Gatzoulis MA, Adatia I, et al. Updated clinical classification of pulmonary hypertension. *J Am Coll Cardiol*. 2013;62(25 Suppl):D34-D41.