

Revatio® (sildenafil) injection



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

FDA-approved Indications

- Revatio® (sildenafil) injection is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to improve exercise ability and delay clinical worsening.

Approved Off-Label Compendial Use

- None

Coverage Guidelines

Pulmonary Arterial Hypertension

The individual must meet **all** of the following criteria for approval:

- Will **not** be using nitrate medications or Adempas (riociguat) concurrently with Revatio® (sildenafil) injection
- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization
- New York Heart Association (NYHA) functional classification of physical activity is classified by one of the following:
 - o Class II – slight limitation of physical activity due to symptoms
 - o Class III - marked limitation of physical activity due to symptoms. Comfortable at rest.
- Disease etiology is classified by one of the following:
 - o Idiopathic pulmonary arterial hypertension
 - o Pulmonary arterial hypertension associated with connective tissue diseases

Additional Information for Prescribers

- None

References

1. Revatio® prescribing information. NY, NY: Pfizer Inc.: April 2015. <http://labeling.pfizer.com/ShowLabeling.aspx?id=645#S1>. Accessed April 11, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 11, 2017. <https://www.micromedexsolutions.com>
3. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension. *Circulation*. 2009;119:2250-2294. Accessed April 11, 2017. <https://www.ncbi.nlm.nih.gov/pubmed/19332472>
4. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed, Little, Brown & Co, Boston, 1994. p.253. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed, Little, Brown & Co, Boston, 1994. p.253.