

Flolan®, Veletri® (Epoprostenol) injection



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

FDA-approved Indication

- Epoprostenol injection is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to improve exercise capacity.

Approved Off-Label Compendial Use

- None

Coverage Guidelines

Pulmonary Arterial Hypertension

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

- Does **not** have a history of heart failure (HF) caused by a reduced left ventricular ejection fraction
- Does **not** have pulmonary edema
- 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 III - marked limitation of physical activity due to symptoms. Comfortable at rest.
 - o Class IV - unable to carry on any physical activity because of symptoms. Symptoms even while at rest.
- Disease etiology is classified by one of the following:
 - o Idiopathic pulmonary arterial hypertension
 - o Heritable pulmonary arterial hypertension
 - o Pulmonary arterial hypertension associated with connective tissue diseases

Additional Information for Prescribers

- None

References

1. Flolan® prescribing information. Research Triangle Park, NC: GlaxoSmithKline: June 2016. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Flolan/pdf/FL-OLAN-PI-PIL.PDF. Accessed April 11, 2017.
2. Veletri® prescribing information. South San Francisco, CA: Actelion Pharmaceuticals US, Inc. July 2016. https://veletri.com/pdf/veletri_full_prescribing_information_2nd_gen.pdf. Accessed April 11, 2017.
3. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 11, 2017. <https://www.micromedexsolutions.com>
4. 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>
5. 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.