

Flolan®, Veletri® (Epoprostenol) injection



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

FDA-approved Indication

Epoprostenol is a prostanoid vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

Approved Off-label Compendial Use

Chronic thromboembolic pulmonary hypertension (CTEPH)

Coverage Guidelines

Pulmonary Arterial Hypertension (PAH)

For initial authorization, the individual must meet the following criteria for approval:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization; AND
- Has New York Heart Association (NYHA) functional class III or IV; OR
- For functional class II, an individual is currently receiving or has tried one oral agent OR has tried one inhaled/parenteral prostacyclin product for PAH; AND
- Epoprostenol is prescribed by or in consultation with a pulmonologist or a cardiologist.
- For idiopathic PAH, an individual must also meet one of the following:
 - Had an acute response to vasodilator testing during the right heart catheterization and has tried at least one calcium channel blocker (CCB) therapy; OR
 - Did not have an acute response to vasodilator testing; OR
 - Cannot undergo a vasodilator test; OR
 - Cannot take CCB therapy (e.g., right heart failure, decreased cardiac output); OR
 - Has tried one CCB.

For re-authorization, the individual must meet **all** of the following criteria for approval:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization; AND
- Epoprostenol is prescribed by or in consultation with a pulmonologist or a cardiologist.

A short-term supply of epoprostenol for up to 30 days will be approved if the patient does not meet the criteria above or if there is insufficient information available.

- Is continuing to benefit from epoprostenol therapy (e.g., improving in functional class, or quality of life, or in other hemodynamic or clinical parameters).

Chronic Thromboembolic Pulmonary Hypertension

- Epoprostenol is prescribed by or in consultation with a pulmonologist or a cardiologist; AND
- For re-authorization, the individual continues to benefit from epoprostenol therapy (e.g., improving in functional class, or quality of life, or in other hemodynamic or clinical parameters).

Approval Duration (initial & renewal): 12 months

Dosing Recommendations

Pulmonary Arterial Hypertension (PAH)

Approve up to 100 nanograms per kilogram per minute intravenously.

Chronic Thromboembolic Pulmonary Hypertension

Approve up to 45 nanograms per kilogram per minute intravenously.

References

1. Flolan® injection for intravenous use [prescribing information]: Research Triangle Park: NC; GlaxoSmithKline; December 2019.
 2. Epoprostenol sodium for injection [prescribing information]. North Wales, PA: Teva; March 2019.
 3. Veletri® injection [prescribing information]. South San Francisco, CA: Actelion; December 2018.
 4. Condliffe R, Kiely DG, Gibbs SR, et al. Improved outcomes in medically and surgically treated chronic thromboembolic pulmonary hypertension. *Am J Respir Crit Care Med*. 2008;177:1122-1127.
 5. Bresser P, Fedullo PF, Auger WR, et al. Continuous epoprostenol for chronic thromboembolic pulmonary hypertension. *Eur Respir J*. 2004; 23:595-600.
 6. Cabrol S, Souza R, Jais X, et al. Intravenous epoprostenol in inoperable chronic thromboembolic pulmonary hypertension. *J Heart Lung Transplant*. 2007;26(4):357-362.
 7. McLaughlin VV, Archer SL, Badesch DB, et al. 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. *J Am Coll Cardiol*. 2009;53:1573-1619.
 8. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and Expert Panel Report. *CHEST*. 2019;155(3):565-586.
 9. Kim NH, Delcroix M, Jais X, et al. Chronic thromboembolic pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801915.
 10. Hoeper MM, Madani MM, Nakanishi N, et al. Chronic thromboembolic pulmonary hypertension. *Lancet Respir Med*. 2014;2(7):573-582.
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