

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)

The recommended dose is up to 100 nanograms per kilogram per minute intravenously.

Chronic Thromboembolic Pulmonary Hypertension

The recommended dose is up to 45 nanograms per kilogram per minute intravenously.

References

1. Flolan® intravenous infusion [prescribing information]: Research Triangle Park: NC; GlaxoSmithKline; August 2021.
2. Epoprostenol sodium intravenous infusion [prescribing information]. North Wales, PA: Teva; March 2019.
3. Veletri® intravenous infusion [prescribing information]. South San Francisco, CA: Actelion/Janssen; July 2022.
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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.
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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.
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11. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022 Aug 26. [Online ahead of print].
12. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2021 report). © 2020 Global Initiative for Chronic Obstructive Lung Disease. Available at: https://goldcopd.org/wp-content/uploads/2020/11/GOLD-REPORT-2021-v1.1-25Nov20_WMV.pdf. Accessed on August 5, 2022.