

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. Studies establishing effectiveness include predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease.

Approved Off-Label Compendial Use

- Chronic thromboembolic pulmonary hypertension (CTEPH)

Coverage Guidelines

Pulmonary Arterial Hypertension (PAH)

For an initial authorization, the individual must meet 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 has had acute vasodilator test done during the right heart catheterization unless he/she was unable to undergo a vasodilator test and meet one of the following:
 - o Had an acute response to vasodilator testing and has tried at least one calcium channel blocker (CCB) therapy unless he/she was unable to take CCB therapy **OR**
 - o Did not have an acute response to vasodilator testing

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

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

Duration of Approval (initial & renewal): 6 months

Dosing Recommendation

The recommended initial dose is 2 ng/kg/min and increased in increments of 1- 2 ng/kg/min at intervals of at least 15 minutes based on clinical response.

References

1. Flolan® injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2018.
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3. Veletri® injection [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals; December 2018.
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