

Epoprostenol Injection (Flolan®, Veletri®, generic)

When requesting epoprostenol injection, the individual requiring treatment must be diagnosed with the following 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)

The individual must meet the following criteria for initial authorization:

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

The individual must meet both of the following criteria for re-authorization:

- 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.

Chronic Thromboembolic Pulmonary Hypertension

The individual must meet the following criterion for authorization:

- Epoprostenol is prescribed by or in consultation with a pulmonologist or a cardiologist.

Approval Duration (initial & renewal): 12 months

Dosing Recommendations

Pulmonary Arterial Hypertension (PAH)

Epoprostenol is administered by continuous intravenous. Infusion of epoprostenol should be initiated at 2 ng/kg/min and increased in increments of 2 ng/kg/min every 15 minutes or longer until a tolerance limit to the drug is established or further increases in the infusion rate are not clinically warranted.

Chronic Thromboembolic Pulmonary Hypertension

The recommended dose is up to 45 ng/kg/min intravenously.

References

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2. Epoprostenol sodium intravenous infusion [prescribing information]. Cranbury, NJ: Sun; January 2021.
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