

## epoprostenol

### Medical Benefit Drug Policy

epoprostenol (Flolan)

epoprostenol (Veletri)

#### Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Administration

### Drug Details

**USP Category:** RESPIRATORY TRACT/PULMONARY AGENTS

**Mechanism of Action:** Prostacyclin vasodilator

#### HCPCS:

J1325:Injection, epoprostenol, 0.5 mg

#### How Supplied:

0.5 mg or 1.5 mg of epoprostenol powder in a single-dose vial

### Condition(s) listed in policy *(see coverage criteria for details)*

- Pulmonary Arterial Hypertension WHO Group I

The following conditions do not meet the safety and efficacy criteria established by Blue Shield of California's Pharmacy & Therapeutics committee and are not covered:

- Aerosolized and nebulized forms of Flolan or generic epoprostenol are not commercially available. We do not cover the compounded version for any indication.

### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

### Coverage Criteria

**The following condition(s) require Prior Authorization/Preservice.**

#### Pulmonary Arterial Hypertension WHO Group I

**Meets medical necessity if all the following are met:**

1. WHO Group I

#### **Covered Doses:**

2 ng/kg/min until dose-limiting pharmacologic effects are elicited or until a tolerance limit to drug is established. This drug is given as a continuous infusion and is titrated to effect.

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

I27.0, I27.21

**Additional Information**

**Clinical classification of pulmonary hypertension (6<sup>th</sup> World Symposium on Pulmonary Hypertension)**

<b>1 PAH</b>
1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4 PAH associated with:
1.4.1 Connective tissue disease
1.4.2 HIV infection
1.4.3 Portal hypertension
1.4.4 Congenital heart disease
1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
1.7 Persistent PH of the newborn syndrome
<b>2 PH due to left heart disease</b>
2.1 PH due to heart failure with preserved LVEF
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH
<b>3 PH due to lung diseases and/or hypoxia</b>
3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders
<b>4 PH due to pulmonary artery obstructions</b>
4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
<b>5 PH with unclear and/or multifactorial mechanisms</b>

- 5.1 Haematological disorders
- 5.2 Systemic and metabolic disorders
- 5.3 Others
- 5.4 Complex congenital heart disease

## References

1. AHFS therapeutic class: Vasodilating Agent. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Flolan (epoprostenol sodium) [Prescribing Information]. Durham, NC: GlaxoSmithKline; 10/2023.
4. Gatzoulis A, Krowka M, Williams PG, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension European Respiratory Journal 2019, 53 (1) 1-13.
5. Humbert M, Kovacs G, Hoeper M, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory distress (ERN-LUNG). European Heart Journal, 2022; 43 (38): 3618-3731. <https://doi.org/10.1093/eurheartj/ehac237>
6. Veletri (epoprostenol) [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US Inc.; 7/2022.

## Review History

Date of Last Annual Review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*