

## treprostinil (Tyvaso)

### Medical Benefit Drug Policy

#### Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

#### Drug Details

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

**Mechanism of Action:** A synthetic analog of prostacyclin

#### HCPCS:

C9399, J3490:Treprostinil, inhalation solution (Medi-Cal)

#### How Supplied:

Sterile solution for oral inhalation: 2.9 mL ampule containing 1.74 mg treprostinil (0.6 mg per mL)

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

- Pulmonary Arterial Hypertension WHO Group I
- Pulmonary Hypertension Associated with Interstitial Lung Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

#### 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:**

Inhalation treatment: Up to 72 mcg per treatment session administered in up to four treatment sessions per day

#### **Covered Doses:**

Inhalation treatment: Up to 72 mcg per treatment session administered in up to four treatment sessions per day [max of 1 ampule (1.74 mg) per day]

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

I27.0, I27.21

**Pulmonary Hypertension Associated with Interstitial Lung Disease****Meets medical necessity if all the following are met:**

1. Patient has interstitial lung disease
2. Prescribed by or in consultation with a pulmonologist

**Covered Doses:**

Inhalation treatment: Up to 72 mcg per treatment session administered up to four treatment sessions per day [max of 1 ampule (1.74 mg) per day]

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

I27.23, J17, J61, J67.9, J84.10, J84.111, J84.112, M34.81

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

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|--|
| <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. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Gatzoulis A, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension European Respiratory Journal 2019, 53 (1) 1-13.
4. 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.
5. Tyvaso (treprostinil) [Prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; 5/2022.

## Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

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