Pulmonary Arterial Hypertension: Inhaled Prostacyclins Utilization Management Criteria

Therapeutic Class:	Pulmonary Arterial Hypertension: Inhaled Prostacyclins
Non-Preferred Agents:	Tyvaso (treprostinil), Tyvaso DPI (treprostinil), Yutrepia (treprostinil)
Preferred Agents:	None
Implementation Date:	1/1/2026
Prepared For:	CT
PDL Status:	Non-preferred
Purpose:	Pulmonary hypertension (PH) is a disease characterized by elevated pulmonary artery pressure. The World Health Organization (WHO) classifies patients with PH into five groups: Group 1 (pulmonary arterial hypertension [PAH]), Group 2 (PH due to left heart disease), Group 3 (PH due to chronic lung disease and/or hypoxemia), Group 4 (PH due to pulmonary artery obstructions), Group 5 (PH due to unclear mechanisms). PAH is a progressive disease characterized by dyspnea, fatigue, syncope, and edema. Patients with PAH are typically evaluated for baseline risk of disease progression and death prior to the selection of therapy; risk stratification determines initial treatment regimen selection. PAH-specific agents include prostacyclin pathway agents, endothelin-1 receptor antagonists, phosphodiesterase-5 inhibitors, a soluble guanylyl cyclase stimulator, an activin-signaling inhibitor, or, more rarely used, calcium channel blockers. The inhaled prostacyclins in table 1 are synthetic prostacyclin analogs that mimic the actions of endogenous prostacyclin, resulting in the dilation of pulmonary and systemic arterial vascular beds. Approved uses for these agents include World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) and WHO Group 3 pulmonary hypertension associated with interstitial lung disease (PH-ILD) (treprostinil only). Safety concerns with inhaled prostacyclins include the risk of bronchospasm, bleeding due to platelet inhibition, hypotension. Common side effects include cough, headache, dizziness and throat irritation. Generics are not available for any agent in this category. As of March 2025, Ventavis is no longer being sold due to discontinuation of the I-neb® AAD® System.

Table 1. Pulmonary Arterial Hypertension: Inhaled Prostacyclins

Generic Name	Brand Name	Approved Indications	Route of Administration	Generic Availability
Treprostinil	Tyvaso®, Tyvaso DPI®	PAH (WHO Group 1) PH-ILD (WHO Group 3)	Inhaled	N
Treprostinil	Yutrepia™	PAH (WHO Group 1) PH-ILD (WHO Group 3)	Inhaled	N

Abbreviations: DPI, dry powder inhalation; PAH, pulmonary arterial hypertension; PHILD, pulmonary hypertension associated with interstitial lung disease; WHO, World Health Organization

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.

General Approval Criteria:

- Requested quantity in accordance with FDA approved product labelling

Initial Therapy – All the following must be met:

- Claim is for a preferred agent **OR**
- Provider has expertise in treating patients with pulmonary hypertension **AND**
- Documented diagnosis of pulmonary hypertension associated with interstitial lung disease **OR**
- Documented diagnosis of pulmonary arterial hypertension and inhaled prostacyclin is being selected as an add on treatment due to clinical worsening on current regimen

Initial PA length: 1 year

Exclusion Criteria: Approval criteria not met

Continuation Therapy: Documented compliance on current therapy regimen **AND** Documented continued clinical benefit

Continuation Length: 1 year

References:

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13. Tyvaso. Package insert. United Therapeutics Corp.; 2022.
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15. Yutrepia. Package insert. Liquidia Technologies, Inc.; 2025.

Revision History

Date	Version	Revisions
11/7/2025	V1	Document approved by DSS