

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Pulmonary Arterial Hypertension (PAH) Agents, Prostacyclin Pathway Agonists, Inhaled PDL Edit
<b>First Implementation Date:</b>	May 12, 2010
<b>Proposed Date:</b>	October 17, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Pulmonary arterial hypertension (PAH) is a severe, progressive, and often fatal condition that occurs idiopathically as well as in association with pulmonary, cardiac, and other thoracic conditions. Reliable estimates of the total prevalence of this condition are difficult to obtain because of the diversity of identifiable causes. PAH, formerly known as primary pulmonary hypertension, is characterized by elevations in pulmonary arterial pressure (PAP) to greater than 25 mmHg at rest and greater than 30 mmHg with exercise. The disease occurs when the PAP is abnormally elevated and forces the right side of the heart to progressively work harder when it pumps blood to the lungs. Symptoms include dyspnea, fatigue, chest pain, palpitations, syncope, and edema. Prognosis varies based on the severity of disease, whether right heart failure is present, and response to vasodilator therapy. If left untreated, the disease produces increases in PAP that may lead to right ventricular failure and death. Despite recent developments in the symptomatic treatment of PAH, there is still no cure.

PAH should be differentiated from pulmonary hypertension secondary to diseases of the heart and lung based on both pathology of the underlying disease and accepted treatments.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Tyvaso®</li> <li>Ventavis®</li> </ul>	<ul style="list-style-type: none"> <li>Tyvaso DPI™</li> </ul>

**Type of Criteria:** ☐ Increased risk of ADE  
☒ Appropriate Indications

☒ Preferred Drug List  
☐ Clinical Edit

**Data Sources:** ☐ Only Administrative Databases

☒ Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Pulmonary Arterial Hypertension (PAH) Agents, Prostacyclin Pathway Agonists, Inhaled
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documented diagnosis of pulmonary hypertension **AND**
- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agent
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Tyvaso DPI: documented therapeutic trial of Orenitram® in the past year

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:

☐  
☐

Progress Notes:  
Other:

☐  
☐

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

- Evidence-Based Medicine Analysis: "Primary Pulmonary Arterial Hypertension (PAH) Agents", UMKC-DIC; July 2023.
- Evidence-Based Medicine and Fiscal Analysis: "RESPIRATORY: Pulmonary Arterial Hypertension, Inhaled Prostacyclins", Gainwell Technologies; Last updated July 20, 2023.
- Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults 2018: update of the CHEST Guideline and Expert Panel Report. Chest. 2019; 155(3): 565-586.
- Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp; May 2022.
- Tyvaso DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corp; June 2023.
- Ventavis [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US Inc; March 2022.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.