SmartPA Criteria Proposal

Drug/Drug Class:	Pulmonary Arterial Hypertension (PAH) Agents, Prostacyclin Pathway Agonists, Inhaled PDL Edit
First Implementation Date:	May 12, 2010
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ 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
• Tyvaso® • Ventavis®	• Tyvaso DPI™

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:	☐	Progress Notes:	☐
MedWatch Form:	☐	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 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Pulmonary Hypertension Agents: Inhaled/Injectable – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- 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; May 2022.
- Ventavis [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US Inc; March 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.