

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Pulmonary Arterial Hypertension and Related Lung Disease – Inhaled Prostacyclin Products Preferred Specialty Management Policy
- Tyvaso® (treprostinil inhalation solution – United Therapeutics)
 - Tyvaso DPI™ (treprostinil inhalation powder – United Therapeutics/Mannkind)
 - Ventavis® (iloprost inhalation solution – Actelion/Janssen)

REVIEW DATE: 10/12/2022; selected revision 11/30/2022

OVERVIEW

Tyvaso, Tyvaso DPI, and Ventavis are inhaled prostacyclin vasodilators (prostacyclin mimetics) indicated for the treatment of:¹⁻³

- **Pulmonary arterial hypertension (PAH), World Health Organization (WHO) Group 1.** Tyvaso and Tyvaso DPI are specifically indicated to improve exercise ability whereas Ventavis is indicated to improve a composite endpoint consisting of exercise tolerance, symptoms, and lack of deterioration.

Tyvaso and Tyvaso DPI are also indicated for:¹

- **Pulmonary hypertension associated with interstitial lung disease (WHO Group 3).** Tyvaso and Tyvaso DPI are indicated to improve exercise ability for this population.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product(s). For all Medications (Preferred and Non-Preferred), the patient is required to meet the respective Prior Authorization Policy criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year in duration. If the patient meets the standard *Pulmonary Arterial Hypertension and Related Lung Disease – Inhaled Prostacyclin Products Prior Authorization Policy* criteria but has not tried the Preferred Product, approval for the Preferred Product(s) will be authorized.

Automation: None.

Preferred Product: Tyvaso, Tyvaso DPI
Non-Preferred Product: Ventavis

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Ventavis	<ol style="list-style-type: none">1. Approve for 1 year if the patient meets both of the following (A and B):<ol style="list-style-type: none">A) Patient meets the standard <i>Pulmonary Arterial Hypertension – Inhaled Prostacyclin Products Prior Authorization Policy</i> criteria; ANDB) Patient meets one of the following (i, ii, or iii):<ol style="list-style-type: none">i. Patient has been established on Ventavis; ORii. Patient has tried Tyvaso or Tyvaso DPI; ORiii. Patient already has the device for Ventavis.2. For a patient who meets the standard <i>Pulmonary Arterial Hypertension and Related Lung Disease – Inhaled Prostacyclin Products Prior Authorization Policy</i> criteria but does not meet 1B, approve the Preferred Product.

REFERENCES

1. Tyvaso® inhalation solution [prescribing information]. Research Triangle Park, NC: United Therapeutics; May 2022.
2. Ventavis® inhalation solution [prescribing information]. Titusville, NJ: Actelion/Janssen; March 2022.
3. Tyvaso DPI™ oral inhalation powder [prescribing information]. Danbury, CT and Research Triangle Park, NC: MannKind and United Therapeutics; May 2022.