Treprostinil Oral Inhalation Solution (TYVASO), Dry Powder Inhaler (TYVASO DPI), and Dry Powder Inhaler (YUTREPIA) for Pulmonary Arterial Hypertension (PAH) Criteria for Use August 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care provided by a VA/ VA Community Care provider experienced in the management of PAH
- ☐ Definitive PAH confirmed by right-heart catheterization and hemodynamic diagnosis: mean pulmonary artery pressure greater than 20 mmHg, pulmonary capillary wedge pressure 15 mmHg or less, and pulmonary vascular resistance greater than 2 Wood units
- ☐ World Health Organization (WHO) Group 1 PAH
- ☐ Patient with unacceptable or deteriorating clinical status on PAH-directed therapy with or who is not a candidate for an ERA and PDE5i^1^2

Additional Inclusion Criteria

If applicable, the following criteria must be met.

- ☐ P**atients who require more than one cartridge or capsule per dose using the DPI** (e.g., >64 mcg of TYVASO or >106 mcg of YUTREPIA), the nebulized solution is preferred. DPIs should be reserved for patients with documented inability to use the nebulized product.^3

1. Endothelin receptor antagonist (ERA) = ambrisentan, bosentan, macitentan; phosphodiesterase-5 inhibitor (PDE5i) = tadalafil, sildenafil
2. Efficacy was established in patients with NYHA Functional Class III symptoms.
3. Cases should be adjudicated on an individual basis at the facility level.

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