Inhaled Prostacycline Mimetic™
Tyvaso®, Ventavis®

FDA INDICATIONS AND USAGE[1,2]

Tyvaso® is a prostacyclin mimetic indicated for the treatment of Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability and Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.

Ventavis® is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration.

APPROVAL CRITERIA[1,2,3,4]

Tyvaso® and Ventavis®[1,2,3,4]

1. Patient's age is to FDA label **AND**;
2. Prescribed by or in consultation with a cardiologist or pulmonologist **AND**;
3. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH) confirmed by right heart catheterization with the following parameters:
    a. Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg **AND**;
    b. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg **AND**;
    c. Pulmonary vascular resistance (PVR) > 3 Wood units **AND**;
4. Baseline in the 6-minute walk distance has been obtained or deemed inappropriate by the prescriber **AND**;
5. Patient has one of the following:
    a. Functional Class III or IV **OR**;
    b. Functional Class II having tried and failed or has a contraindication to both:
        i. Sildenafil or tadalafil **AND**;
        ii. One other oral agent indicated for PAH (I.E. bosentan, macitentan,, trepostinil, etc.)

Tyvaso® only[1,5,6]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a cardiologist or pulmonologist **AND**;
3. Patient has a diagnosis of World Health Organization (WHO) Group 3 interstitial lung disease associated with pulmonary hypertension confirmed by right heart catheterization with the following parameters:
    a. Pulmonary vascular resistance (PVR) ≥ 4 WU
    b. Mean pulmonary artery pressure (PAP) of ≥ 30 mmHg
    c. Pulmonary capillary wedge pressure (PCWP) ≤ 12 mmHg if PVR ≥ 4 WU to < 6.25 WU OR PCWP ≤ 15 mmHg if PVR ≥ 6.25WU **AND**;
4. Baseline in the 6-minute walk distance has been obtained or deemed inappropriate by the prescriber.

DENIAL CRITERIA [1,2,3,4,5,6]

1. Failure to meet approval criteria.

CAUTIONS[1,2]

- May cause symptomatic hypotension and has the potential to increase the hypotensive effect of vasodilators and antihypertensive agents
- There is a potential for increased risk of bleeding, particularly in patients maintained on anticoagulants.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months if the prescriber documents that the patient has shown improvement or is stable from baseline in the 6-minute walk distance test **OR** if 6-minute is not appropriate the functional class has improved or remained stable.

QUANTITY LIMIT

- 34 day supply

REFERENCES / FOOTNOTES:

1. Tyvaso® inhalation solution [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; October 2017.
2. Ventavis® inhalation solution [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals; December 2019.
3. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and Expert Panel Report. CHEST. 2019;155(3):565-586.
4. McLaughlin VV, Arther SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: A report of the American College of Cardiology Foundation task force on expert consensus documents and the American Heart Association. Circulation 2009:199:2250-94.
5. King CS, Shlobin OA. The trouble with Group 3 pulmonary hypertension in interstitial lung disease. Dilemmas in diagnosis and the conundrum of treatment. CHEST. 2020;158(4):1651-1664.
6. Shioleno AM, Ruopp NF. Group 3 pulmonary hypertension: a review of diagnostics and clinical trials. Clin Chest Med. 2021;42:59-70.