



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Iloprost

Brand Name: Ventavis

Medication Class: Prostanoid

FDA Approved Uses: Treatment of pulmonary hypertension (WHO group I) in patients with the New York Heart Association (NYHA) Class III or IV symptoms.

Available Dosage Forms: Inhalation Solution is supplied in cartons of 30 or 100 clear glass single-use ampules (20 mcg iloprost per 2 mL ampule):

Usual Dose: First inhaled dose should be 2.5mcg, if tolerated, dosing should be increased to 5.0 mcg and maintained at that dose. If 5.0 mcg is not tolerated, dosing should be reduced to and maintained at 2.5mcg. Patient should be maintained at the maximum tolerated dose. Ventavis should be taken 6-9 times per day (no more than once every 2 hours) during waking hours.

Duration of Therapy: indefinite

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed pulmonary hypertension (WHO group I).
Note: WHO Group I comprises:
 - Idiopathic PAH,
 - Familial PAH,
 - PAH associated with related conditions (e.g., collagen vascular disease, congenital systemic-to-pulmonary shunts, portal hypertension, HIV infection, drugs and toxins, etc.),
 - PAH associated with significant venous or capillary involvement,
 - Persistent pulmonary hypertension of the newborn.
- Patient has NYHA class III or IV symptoms.
- Patients must be educated on how to use their nebulizer properly.
- Failed / intolerant to bosentan (Tracleer).

Cautions:

- Those with at least Child Pugh Class B hepatic impairment.
- Those on dialysis.
- Direct mixing of other meds with iloprost has not been evaluated.

Contraindications:

- None known.



Not Approved if:

- Patient does not meet the above stated criteria.

Special Considerations:

- Has not been adequately studied with concomitant use of other approved therapies for PAH.
- Inhalation by the Prodose AAD (adaptive aerosol delivery) system which is a pulmonary drug device, and only the Prodose AAD system has been proven to deliver a safe and accurate dose of Ventavis.
- Ventavis is primarily an outpatient therapy initially administered under the care of a healthcare professional.
- Increased risk of syncope, manufacturer recommends monitoring vital signs while initiating iloprost, especially in patients with low systemic blood pressure. (rebound before next dose, problem waking up in am, must get up slowly)

P&T Approval: _____ Date: _____