



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST

Generic	Brand	HICL	GCN	Exception/Other
ILOPROST	VENTAVIS	26287		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
 - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 - Documented confirmatory hypertension pulmonary arterial (PAH) diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
 - The patient has NYHA/WHO Functional Class III-IV symptoms

If yes, **approve up to 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **ILOPROST (Ventavis)** requires a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). The following criteria must also be met.

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
- The patient has NYHA/WHO Functional Class III-IV symptoms.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **ILOPROST (Ventavis)** renewal requires a diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1 with WHO Class III-IV symptoms. The following criteria must also be met:

- The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
- The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE

Ensure appropriate use of Ventavis.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g., diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

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FDA APPROVED INDICATION

VENTAVIS is indicated for treatment of pulmonary artery hypertension (WHO group 1) in patients with NYHA/WHO class III or IV symptoms to improve exercise capacity.

World Health Organization Classification of Pulmonary Hypertension Group 1:

- Idiopathic (familial)
- Congenital systemic-to-pulmonary shunts
- HIV infection
- Collagen vascular disease
- Portal Hypertension
- Drugs and toxins

REFERENCES

- Actelion. Ventavis® (iloprost) prescribing information. South San Francisco, CA. April 2013.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/16

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P&T Approval: 08/16