

Commercial/Healthcare Exchange PA Criteria
Effective: 5/11/2018

Prior Authorization: Ventavis (iloprost)

Products Affected: Ventavis (iloprost) oral inhalation solution

Medication Description:

Iloprost is a synthetic analog of prostacyclin PGI₂. Iloprost dilates systemic and pulmonary arterial vascular beds. It also affects platelet aggregation but the relevance of this effect to the treatment of pulmonary hypertension is unknown. The two diastereoisomers of iloprost differ in their potency in dilating blood vessels, with the 4S isomer substantially more potent than the 4R isomer.

Covered Uses: 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.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. World Health Organization (WHO) functional class
3. NYHA Class
4. Previous therapies tried and failed

New York Heart Association functional classification:

Class 1: No symptoms with ordinary physical activity.

Class 2: Symptoms with ordinary activity. Slight limitation of activity.

Class 3: Symptoms with less than ordinary activity. Marked limitation activity.

Class 4: Symptoms with any activity or event at rest

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a pulmonologist or a cardiologist

Coverage Duration: 12 months

Other Criteria:

Pulmonary Arterial Hypertension

- A. Patient has clinically diagnosed primary or secondary PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure); **AND**
- B. Patient exhibits Class III or IV symptoms; **AND**
- C. Patient has tried and failed, or has a contraindication or intolerance to a calcium channel blocker after favorable response to acute vasoreactivity testing; **OR**
- D. Patient has failed to have a pulmonary vasodilator response to an acute challenge of a short acting vasodilator; **AND**
- E. Patient has tried and failed or has a contraindication or intolerance to Tracleer (bosentan).

References:

1. Product Information: VENTAVIS(R) inhalation solution, iloprost inhalation solution. Actelion Pharmaceuticals US Inc (per FDA), South San Francisco, CA, 2019.
2. Iloprost. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated May 14, 2020. Accessed June 18, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Coverage duration increased to 12 months Removal of other criteria: Patient must not be using tobacco products.	All	7/1/2020