

Prior Authorization DRUG Guidelines

VENTAVIS (iloprost)

Effective Date: 10/20/14
Date Developed: 10/14/14
Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Description: VENTAVIS Inhalation Solution is a clear, colorless, sterile solution containing iloprost formulated for inhalation via the I-neb® AAD® (Adaptive Aerosol Delivery) System. Iloprost is a synthetic analog of prostacyclin PGI2 which dilates systemic and pulmonary arterial vascular beds.

Authorization Criteria: Treatment of pulmonary arterial hypertension (WHO Group I) in patient with NYHA class III or IV symptoms to improve exercise tolerance, symptoms, and diminish clinical deterioration.

Unlabeled Use: WHO group III and IV pulmonary arterial hypertension

Note: Per VCHCP policy, unlabeled uses are not covered unless specific information is submitted. See VCHCP Policy on Coverage of Prescription Medication for Off-Label Use.

Dosing: 2.5-5.0 mcg 6-9 times a day while awake, no more than once every 2 hours

How Supplied: 1mL ampules 10,20mcg/mL

Contraindications/Warnings: Do not mix with other medications;

Major Adverse Reactions: Bronchospasm; cough; headache; paradoxical increase in pulmonary vascular resistance

Major Drug Interactions: Increased risk of bleeding in patients maintained on anticoagulants or platelet inhibitors

REFERENCES

- 1. Badesch DB, Abman SH, Simonneau G, et al, "Medical Therapy for Pulmonary Arterial Hypertension: Updated ACCP Evidence-Based Clinical Practice Guidelines," *Chest*, 2007, 131(6):1917-28.
- 2. Baghetti M, Reber G, de Moerloose P, et al, "Aerosolized Iloprost Induces a Mild but Sustained Inhibition of Platelet Aggregation," *Eur Respir J*, 2002, 19(3):518-24.
- 3. Emmel M, Keuth B, and Schickendantz S, "Paradoxical Increase of Pulmonary Vascular Resistance During Testing of Inhaled Iloprost," *Heart*, 2004, 90(1):e2.



- 4. Humbert M, Sitbon O, and Simmoneau G, "Treatment of Pulmonary Arterial Hypertension," *N Engl J Med*, 2004, 351(14):1425-36.
- 5. McLaughlin VV, Archer 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: Developed in Collaboration with the American College of Chest Physicians, American Thoracic Society, Inc, and the Pulmonary Hypertension Association," *J Am Coll Cardiol*, 2009, 53(11):1573-619.
- 6. Olschewski H, Hoeper MM, Behr J, et al, "Long-Term Therapy With Inhaled Iloprost in Patients With Pulmonary Hypertension," *Respir Med*, 2010, 104(5):731-40.
- 7. Olschewski H, Rohde B, Behr J, et al, "Pharmacodynamics and Pharmacokinetics of Inhaled Iloprost, Aerosolized by Three Different Devices, in Severe Pulmonary Hypertension," *Chest*, 2003, 124(4):1294-304.
- 8. Olschewski H, Simonneau G, Galie N, et al, "Inhaled Iloprost for Severe Pulmonary Hypertension," *N Engl J Med*, 2002, 347(5):322-9.
- 9. <u>www.uptodate.com</u>: Iloprost: Drug Guidelines

Revision History:

Date Approved by P&T Committee: 10/28/14; QAC 11/25/14 Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check
			MCG