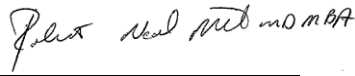


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Approved: **Robert Neal Mills, MD** Date: 03/28/12

Description: Inhaled nitric oxide (iNO) improves gas exchange, decreases inflammation, and is a selective pulmonary vasodilator. It was approved by the FDA in 1999 as a treatment for persistent pulmonary hypertension in infants. Its use has expanded to other conditions such as management of pulmonary hypertension in repair of congenital heart disease and during heart catheterization to determine pulmonary vasoreactivity. iNO therapy is used in conjunction with ventilatory support to treat pulmonary hypertension in neonatal patients, post meconium aspiration, and related birth defects.

Criteria:

Note: Use of iNO therapy for more than 4 days is subject to medical necessity review.

- A. ODS considers iNO therapy medically necessary for any of the following conditions:
1. Hypoxic respiratory failure in term and near term infants with a gestational age of at least 34 weeks when all of the following criteria are met:
 - a. Absence of a congenital diaphragmatic hernia.
 - b. Failure, contraindication to, or intolerance to conventional therapy (high-frequency ventilation, high concentrations of oxygen, hyperventilation, alkalosis induction, neuromuscular blockade, or sedation) or is expected to fail.
 2. Diagnostic use of iNO as a method of assessing pulmonary vasoreactivity in patients with pulmonary hypertension.
 3. For postoperative management of pulmonary hypertension following repair of congenital heart disease.
- B. ODS considers all other indications for iNO therapy experimental and investigational. iNO for indications other than those listed above have not been identified as widely used and generally accepted in nationally recognized peer-reviewed medical literature.

Information to be Submitted with Pre-Authorization Request:

- Chart notes from ordering specialist including history and physical
- Treatment history
- Treatment plan

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