



## *Nitric Oxide and ECMO Treatment*

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### **Purpose:**

To provide treatment of neonates with nitric oxide or ECMO guidelines for the Medical Department staff to reference when making benefit determinations.

### ***Definitions***

- Inhaled nitric oxide (iNO) is a selective pulmonary vasodilator without significant effects on the systemic circulation. It is administered through specialized ventilatory equipment in order to improve oxygenation and ventilation, thus reducing the need for extracorporeal membrane oxygenation (ECMO), and lowering the incidence of chronic lung disease and death among infants with respiratory failure.
- ECMO is similar to cardiopulmonary bypass, as used during cardiac surgery, but is modified for prolonged use at the bedside intensive care unit and can provide prolonged mechanical support for patients with reversible heart or lung failure. The technology is capable of effectively and safely supporting respiration and circulation in neonates with severe reversible respiratory failure and a moribund clinical presentation.

### ***Coverage Guidelines***

- A) Nitric Oxide therapy can be considered medically necessary as a component of the treatment of hypoxic respiratory failure in neonates 34 weeks gestation or greater when both of the following criteria are met:
- 1) Neonates do not have congenital diaphragmatic hernia; AND
  - 2) When conventional therapies such as administration of high concentrations of oxygen, hyperventilation, high-frequency ventilation, the induction of alkalosis, neuromuscular blockade, and sedation have failed or are expected to fail.



## ***Nitric Oxide and ECMO Treatment***

B) *ECMO* can be considered medically necessary in neonates who meet *ALL* of the following criteria:

1) Diagnosis of any of the following:

- Congenital diaphragmatic hernia; or
- Hyaline membrane disease; or
- Meconium aspiration; or
- Persistent fetal circulation; or
- Possible cardiac anomaly; or
- Refractory neonatal septic shock; or
- Respiratory distress syndrome; or
- Uncontrollable air leak;

*AND*

- 2) Gestational age of 34 weeks or greater; *and*
- 3) Birth weight of 2,000 grams or greater; *and*
- 4) Age less than 10 days (preferably less than 7 days).

### ***Exclusion Criteria***

- Nitric Oxide therapy is considered experimental and investigational for all other indications in infants, children, and adults including, but not limited to the following:
  - Acute bronchiolitis
  - Acute hypoxemic respiratory failure
  - Acute pulmonary embolism
  - Acute respiratory distress syndrome or acute lung injury
  - Bronchopulmonary dysplasia, prevention in preterm infants without hypoxic respiratory failure
  - Lung transplantation, prevention of ischemia-reperfusion injury/acute rejection following lung transplantation
  - Malaria, adjunctive treatment
  - Sickle cell disease, treatment of vaso-occlusive crises or acute chest syndrome (sickle cell vasculopathy)
  - Treatment of persons with congenital diaphragmatic hernia
- Any other use of *ECMO* for neonates is considered experimental and investigational.

### **References:**

1. National Institutes of Health. NIH Consensus and State of the Science Statement. Inhaled Nitrous Oxide Therapy for Premature Infants; Vol. 27, No. 5. Oct. 27 – 29, 2010.
2. Mugford M, Elbourne D, Field D. Extracorporeal membrane oxygenation for severe respiratory failure in newborn infants. Cochrane Database Syst Rev. 2008;(3):CD001340.



### ***Nitric Oxide and ECMO Treatment***

3. Brierley J, Carcillo JA, Choong K, et al. Clinical practice parameters for hemodynamic support of pediatric and neonatal septic shock: 2007 update from the American College of Critical Care Medicine. *Crit Care Med.* 2009;37(2):666-688.
4. Keckler SJ, Laituri CA, Ostlie DJ, St Peter SD. A review of venovenous and venoarterial extracorporeal membrane oxygenation in neonates and children. *Eur J Pediatr Surg.* 2010;20(1):1-4.
5. Rajagopal SK, Almond CS, Laussen PC, et al. Extracorporeal membrane oxygenation for the support of infants, children, and young adults with acute myocarditis: A review of the Extracorporeal Life Support Organization registry. *Crit Care Med.* 2010;38(2):382-387.

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