

Treatment of Neonates with Nitric Oxide or ECMO

Origination: 09/23/11	Revised:	Annual Review: 12/15/11
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Treatment of Neonates with Nitric Oxide or ECMO in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

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.

Eligibility Criteria

- A) *iNO therapy* can be considered medically necessary as a component of the treatment of hypoxic respiratory failure in term and near term neonates born at 34 or more weeks of gestation when conventional therapies such as administration of high concentration of oxygen, hyperventilation, high-frequency ventilation, the induction of alkalosis, neuromuscular blockade, and sedation have failed or are expected to fail. There are rare clinical situations, including pulmonary hypertension, or hypoplasia, that have been inadequately studied in which inhaled nitric oxide may have benefit in infants <34 weeks gestation.

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Recommendation, continued:

Eligibility Criteria, continued

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).

Exclusions

- Any other use of *iNO therapy* including use in neonates born at 34 or fewer weeks of gestation is considered experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.
- 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.
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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