Nitric Oxide and ECMO Treatment

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Line of Business: Commercial Only ☐ QHP/Exchange Only ☐ Medicare Only ☐ Commercial & QHP/Exchange ☐ Commercial, QHP/Exchange, & Medicare ☒		

Purpose:

To provide treatment of neonates with nitric oxide or ECMO guidelines for Population Health and Provider Alliances associates 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 Members 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.

B) *ECMO* can be considered medically necessary in neonates who meet *ALL* of the following criteria:
   1) Diagnosis of any of the following:
      a. Congenital diaphragmatic hernia
      b. Hyaline membrane disease
      c. Meconium aspiration
      d. Persistent fetal circulation
      e. Possible cardiac anomaly
      f. Refractory neonatal septic shock
      g. Respiratory distress syndrome

2) Uncontrollable air leak;
3) Gestational age of 34 weeks or greater; *and*
4) Birth weight of 2,000 grams or greater; *and*
5) 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 in infants, children, and adults including, but not limited to the following:
  - Acute bronchiolitis
  - Acute hypoxemic respiratory failure
  - Acute pulmonary embolism
  - Acute respiratory distress system 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:

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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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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.