Treatment of Neonates with Nitric Oxide or ECMO

| Origination: 09/23/11 | Revised: 07/31/14 | Annual Review: 11/12/15 |

**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) *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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**Coverage Guidelines, 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;

\textit{AND}

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

**Exclusion Criteria**

- Any other use of \textit{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:**

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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.