Medical Policy
Inhaled Nitric Oxide as a Treatment of Hypoxic Respiratory Failure in Neonates

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Policy Number: 100
BCBSA Reference Number: 8.01.37

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members
Inhaled nitric oxide may be MEDICALLY NECESSARY when administered as a component of treatment of hypoxic respiratory failure in neonates born at 34 or more weeks of gestation.

Inhaled nitric oxide is INVESTIGATIONAL in all other instances, including, but not limited to the following:
- Adults and children with acute hypoxemic respiratory failure, or
- For premature neonates born at less than or equal to 34 weeks of gestation.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
Prior authorization is NOT required.

Commercial Members: PPO, and Indemnity
Prior authorization is NOT required.

Medicare Members: HMO BlueSM
Prior authorization is NOT required.

Medicare Members: PPO BlueSM
Prior authorization is NOT required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's
contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

Description
Inhaled nitric oxide (iNO) is an effective treatment in the near-term to full-term neonate diagnosed with persistent pulmonary hypertension (PPHN) as an isolated condition or as an associated condition resulting from any of the following:

- Respiratory distress syndrome (hyaline membrane disease)
- Meconium aspiration syndrome
- Pneumonia
- Sepsis
- Congenital diaphragmatic hernia, or
- Lung hypoplasia.

Nitric oxide acts as a vasodilator which increases blood flow to the tissues and regulates the binding and releasing of oxygen to hemoglobin. When used as an inhalant to treat PPHN nitric oxide produces selective pulmonary vasodilatation and redistributes pulmonary blood flow from areas of the lung with low gas exchange capability (decreased ventilation capacity) to the healthier lung tissue with better gas exchange capability, thus improving oxygenation.

The effect of iNO and ventilator support on improved oxygenation also reduces the need for the use of extracorporeal membrane oxygenation, a more surgically invasive treatment.

Summary
There is evidence from a systematic review of randomized controlled trials that inhaled nitric oxide improves the net health outcome in hypoxic term or near-term infants. Other systematic reviews of randomized controlled trials did not find evidence of a net benefit from inhaled nitric oxide among preterm infants when used in the first 3 days of life for severe respiratory failure or after the first 3 days of life to prevent bronchopulmonary dysplasia.

For preterm infants, the largest trial published to date had 800 participants and did not find that use of inhaled nitric oxide in preterm infants improved survival without bronchopulmonary dysplasia or survival without brain injury.

In children and adults with acute hypoxemic respiratory failure, a systematic review of randomized controlled trials did not find that inhaled nitric oxide treatment improved the net health outcome; there was no significant effect on all-cause mortality or duration of mechanical ventilation. There was no significant difference in adverse events overall, but there was a significantly higher rate of renal impairment with inhaled nitric oxide treatment.

Finally, for postoperative management of children with congenital heart disease, one RCT reported an improvement in pulmonary hypertensive episodes, but a systematic review of RCTs found no significant mortality reduction and a paucity of data on other outcomes. Thus, inhaled nitric oxide may be considered medically necessary to treat term and near-term infants and investigational for other indications.

Policy History

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<tr>
<th>Date</th>
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<tr>
<td>1/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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### Medical policy #100, effective 6/2009, describing covered and non-covered indications.

**Medical policy ICD 10 remediation:** Formatting, editing and coding updates. No changes to policy statements.

**5/2011**
Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.

**4/2011**
Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.

**5/2010**
Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.

**3/2010**
Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.

**6/2009**
Medical policy #100, effective 6/2009, describing covered and non-covered indications.

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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**


