APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well but selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Nitric oxide (NO) inhalation therapy is a minimally invasive treatment that involves inhalation of gaseous NO in conjunction with ventilatory support. INOmax® is a blend of compressed NO (0.1% or 0.8%) and nitrogen (99.9% or 99.2%) gases supplied in aluminum cylinders. In these neonates, NO inhalation at doses of 20 dilates pulmonary blood vessels, improving blood oxygenation and reducing the likelihood that ECMO will be required. Gradual weaning from NO is essential to prevent a rebound increase in arterial pressure and insufficient oxygenation of pulmonary tissue.
POSITION STATEMENT

Applicable To:
☑ Medicaid

Exclusions

The use of inhaled nitric oxide therapy is considered experimental and investigational in the following circumstances:

- Treating premature infants < than 34 weeks of gestation; OR,
- For the treatment of any indication not listed above

Coverage

Inhaled nitric oxide (iNO) therapy is considered medically necessary when the following criteria are met:

1. Neonate must be term and near-term, >= 34 weeks gestational age; AND,
2. Cyanosis and respiratory distress with tachypnea; AND,
3. Hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension; AND,
4. Normal chest x-ray or abnormalities indicative of MAS (meconium aspiration syndrome), CDH (congenital diaphragmatic hernia), pneumonia, hyaline membrane disease; AND,
5. Conventional therapies such as O2 support and mechanical ventilation failed; AND,
6. Pulmonary vascular resistance >=25 vs. 14 mm Hg in normal cases.

Hypoxic respiratory failure defined as an oxygenation index (OI) of at least 25 recorded on 2 measurements made at least 15 minutes apart. The OI is calculated as the mean airway pressure in cm’s water multiplied by the fraction of inspired oxygen divided by the partial pressure of arterial oxygen times 100. An OI of 25 is associated with a 50% risk of requiring ECMO or dying. An OI of 40 is often used as a criterion to initiate ECMO therapy.

Dose and Duration of Treatment

Studies of iNO Therapy show that inhalation of nitric oxide of 20 ppm were found to be effective in most neonates. Increasing the dose to 40 ppm does not increase the efficacy of treatment seen at 20 ppm. Sustained inhalation of NO doses at 80 ppm increases the risk of methemoglobinemia.

Multi-center clinical trials of iNO therapy had a typical duration of less than 5 days, which parallels the clinical resolution of pulmonary hypertension. If iNO therapy is required more than 4 days, medical necessity review is required and an investigation into other possible causes of pulmonary hypertension should be considered (e.g. alveolar capillary dysplasia).

Weaning and Discontinuation of Therapy

Two approaches to weaning off iNO therapy exist and are recommended in the literature.

1. Recommendation that iNO be reduced to 5 ppm in the first 4 to 24 hours after initiating therapy.
   - iNO is started at 20 ppm. Arterial blood gas and methemoglobin are measured at 4, 24, and 96 hours
   - Dose of iNO is decreased to 5 ppm if the neonate’s condition is stable, partial pressure of arterial oxygen (PaO2) is at least 60 mm Hg, and pH is 7.55 or lower
   - If these criteria are not met, dose is maintained at 20 ppm until the criteria are met or until the
   - neonate has been treated for 24 hours
   - After 24 hours, dose is decreased to 5 ppm
   - Treatment is continued at 5 ppm until fraction of inspired oxygen (FIO2) is less than 0.7, the neonate has
   - been treated for 96 hours, or the neonate is 7 days old, whichever comes first

2. An alternative approach recommends that iNO be reduced in a stepwise fashion to as low as 1 ppm before discontinuation in order to minimize reduction in PaO2.
• After the neonate is classified as a treatment success (PaO2 ≥60 mm Hg, FIO2 <0.6, mean airway pressure <10 cm H2O), iNO is reduced by 20%
• An arterial blood gas with a record of hemodynamic and ventilatory status is obtained, and further 20% reductions can be made immediately or within 4 hours
• This weaning process is continued until iNO is turned off
• iNO can be increased back up to 20% with appropriate increases in FIO2 if PaO2 becomes <40 mm Hg during a weaning step

Note: Sudden discontinuation of iNO will cause rebound pulmonary hypertension that may be severe. This probably results from suppression by iNO of endogenous NO production. Rebound pulmonary hypertension is a risk with cessation of iNO from even low doses (i.e., <5 ppm), after only a few hours of iNO therapy, and regardless of whether the infant initially responded to iNO.

CODING

CPT© Code – No applicable codes.

HCPCS Level II ©Code – No applicable codes.

ICD-10-PCS (Inpatient Only)
Refer to the following ICD-10-PCS table(s) for specific code assignment based on physician documentation.

NOTE: Per ICD-10-PCS Coding Guidelines, “ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code”.

3E0F3SD Introduction of Gas into respiratory tract, percutaneous approach
3E0F7SD Introduction of Gas into respiratory tract via natural or artificial opening
3E0F8SD Introduction of Gas into respiratory tract via natural or artificial opening endoscopic

Covered ICD-10-CM Diagnosis Codes
P28.5 Respiratory failure of newborn
P29.3 Persistent fetal circulation
P07.36 Preterm newborn, gestational age 33 completed weeks
P07.37 Preterm newborn, gestational age 34 completed weeks
P07.38 Preterm newborn, gestational age 35 completed weeks
P07.39 Preterm newborn, gestational age 36 completed weeks
P22.0 Respiratory distress syndrome of newborn

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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