MEDICAL POLICY STATEMENT
GEORGIA MEDICAID

Policy Name		Policy Number	Date Effective
Inhaled Nitric Oxide for Neonates		MM-1048	02/01/2021-10/31/2021
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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A. Subject

Inhaled Nitric Oxide for Neonates

B. Background

Nitric oxide (NO) is a lipophilic gas that is naturally produced in numerous cells in the body and is readily absorbed across pulmonary membranes in the ventilated lung after inhalation. When administered via inhalation, it is a potent endogenous vasodilator that induces relaxation of vascular and bronchial smooth muscle and vasodilatation of blood vessels. Inhaled nitric oxide (INO) has been used in conjunction with ventilator support as a treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN), in term or near-term (greater than 34 weeks gestation) neonates to improve oxygenation and decrease the need for extracorporeal membrane oxygenation (ECMO).

C. Definitions

- **Extracorporeal membrane oxygenation (ECMO)** - is temporary support of heart and lung function by partial cardiopulmonary bypass (up to 75% of cardiac output). It is used for patients who have reversible cardiopulmonary failure from pulmonary, cardiac or other disease.
- **Nitric oxide** - Nitric oxide (NO), also called nitrogen monoxide, colorless lipophilic gas that is formed by the oxidation of nitrogen. Nitric oxide performs important chemical signaling functions in humans and other animals and has various applications in medicine.
- **Persistent pulmonary hypertension of the newborn (PPHN)** - is a serious disorder in which the blood flow and the amount of oxygen in the bloodstream is limited due to constriction of the arteries of the lungs after delivery.
- **Hypoxic respiratory failure** - is a serious condition that develops when the lungs can't get enough oxygen into the blood to reach the tissues of the body.
- **Oxygen Index** - Oxygenation index is used to assess severity of hypoxic respiratory failure (HRF) and persistent pulmonary hypertension of the newborn (PPHN). The OI is calculated as the mean airway pressure divided by the partial pressure of arterial oxygen times 100.

D. Policy

I. CareSource will review medical necessity guidelines based on the clinical documentation that is submitted prior to payment of claims.

II. CareSource considers the initiation of iNO therapy as medically necessary for ONE of the following indications (A,B,C):

A. Indicator:

1. Hypoxic respiratory failure; and
2. Neonates ≥ 34 weeks gestational age at birth; and
3. Echocardiographic evidence of PPHN <u>without</u> congenital heart disease that is a ductal dependent lesion(s) ; and one of the following:

a. Conventional therapies (such as mechanical ventilation, administration of high concentrations of oxygen (80-100%), high frequency oscillatory ventilation (HFOV), induction of alkalosis, neuromuscular blockade and sedation) have failed or are expected to fail; or
b. Diagnosis of congenital diaphragmatic hernia (when iNO is used as a bridge to surgical repair).

B. Indicator:
1. Post-operative management of neonates ≥ 34 weeks gestational age at birth including ONE of the following conditions:
a. Pulmonary hypertension following repair of congenital heart disease; or
b. Pulmonary hypertensive crisis following pediatric heart or lung surgery.

C. Indicator:
1. Management of pulmonary hypertension during heart catheterization to determine pulmonary vasoreactivity.

III. iNO administration must be initiated with alternative vasodilator therapies with the intent to wean iNO (e.g. sildenafil or others).

IV. For continued iNO therapy, documentation must be obtained every 48 hours with evidence of re-evaluation for iNO therapy.
A. Conditions for continuation of iNO therapy beyond 48 hours require one of the following:
1. Patient continues to require iNO due to a continued O2 requirement of 80 - 100% FiO2; or
2. A weaning protocol has been initiated after a 4-6 hour period of stability, indicated by a decreasing O2 requirement.

V. If there is a lack of positive response and inability to wean on 20ppm after 48 hrs, discontinuation of iNO therapy should be considered.
A. Documentation of reasons to continue therapy must be submitted.

VI. CareSource considers the use of iNO not medically necessary for the following indications:
A. Preterm infants < 34 weeks gestation at birth.
B. Acute bronchiolitis.
C. Bronchopulmonary dysplasia (BPD).
D. Echocardiogram demonstrating congenital heart disease with ductal dependent lesion(s).

E. Conditions of Coverage

F. Related Policies/Rules

G. Review/Revision History

DATE		ACTION
Date Issued	09/16/2020	
Date Revised		
Date Effective	02/01/2021	New Policy
Date Archived	10/31/2021	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy

H. References

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18. The Neonatal Inhaled Nitric Oxide Study Group. Inhaled Nitric Oxide in Full-Term and Nearly Full-Term Infants with Hypoxic Respiratory Failure. N Engl J Med 1997;336:597-604.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 6/29/2020

GA-MED-P-274053 Date Issued 09/16/2020 DCH Approved 10/28/2020