

Nitric Oxide Therapy - Inhaled (INO Therapy)

Date of Origin: 04/2011

Last Review Date: 10/24/2024

Effective Date: 11/1/2024

Dates Reviewed: 3/12, 12/12, 11/13, 09/14, 10/15, 11/16, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021, 09/2022, 10/2023, 10/2024

Developed By: Medical Necessity Criteria Committee

I. Description

Inhaled nitric oxide (INO) improves gas exchange, decreases inflammation, and is a selective pulmonary vasodilator. It was approved by the FDA in 1999 as a treatment for persistent pulmonary hypertension in infants. Its use has expanded to other conditions such as management of pulmonary hypertension in repair of congenital heart disease and during heart catheterization to determine pulmonary vasoreactivity. INO therapy is used in conjunction with ventilatory support to treat pulmonary hypertension in neonatal patients, post meconium aspiration, and related birth defects.

II. Criteria: CWQI HCS-0038

- A. Moda Health considers INO therapy medically necessary for **1 or more** of the following conditions:
 - a. Hypoxic respiratory failure in term and near-term infants with a gestational age of at least 34 weeks when **All** of the following criteria are met:
 - i. Absence of a congenital diaphragmatic hernia; and
 - ii. Failure, contraindication to, or intolerance to conventional therapy (high-frequency ventilation, high concentrations of oxygen, hyperventilation, alkalosis induction, neuromuscular blockade, or sedation) or is expected to fail.
 - b. Diagnostic use of INO as a method of assessing pulmonary vasoreactivity in patients with pulmonary hypertension.
 - c. For postoperative management of pulmonary hypertensive crisis in infants and children with congenital heart disease.
- B. NOTE – INO therapy is considered medically necessary for no longer than 14 days if the oxygen desaturation has been resolved. Refer to the medical director if INO therapy is requested for more than 14 days
- C. Moda Health considers all other indications for INO therapy experimental and investigational. INO for indications other than those listed above have not been identified as widely used and generally accepted in nationally recognized peer-reviewed medical literature

III. Information Submitted with the Prior Authorization Request:

1. Chart notes from the ordering specialist including history and physical
2. Treatment history
3. Treatment plan

IV. CPT or HCPC codes covered:

Codes	Description
94002	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day
94003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day
94004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day

V. Annual Review History

Review Date	Revisions	Effective Date
12/2012	Annual Review: Added table with review date, revisions, and effective date.	01/01/2013
11/13	Annual Review: No change	11/27/2013
09/14	Annual Review: No change	09/30/2014
07/15	Added ICD-9 and ICD-10 Codes	07/2015
10/15	Annual Review: changed title to Nitric Oxide Therapy – Inhaled, no change to criteria; added ICD10 codes	10/28/2015
11/16	Annual Review – removed ICD-9 codes	11/30/2016
10/2017	Annual Review – moved to new template	10/25/2017
10/2018	Annual Review- no changes	10/2018
10/2019	Annual Review: No changes	11/01/2019
10/2020	Annual Review: No changes	11/02/2020
10/2021	Annual Review: No changes	11/1/2021
09/2022	Annual Review: No changes	10/01/2022
10/2023	Annual Review: No changes	11/1/2023
10/2024	Annual Review: No changes	11/1/2024

VI. References

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outcomes of preterm infants enrolled in the Nitric Oxide (to prevent) Chronic Lung Disease trial. *J Pediatr*. 2008 Oct;153(4):525-9.

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22. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
I27.0	Primary pulmonary hypertension
I27.1	Kyphoscoliotic heart disease
I27.2	Other secondary pulmonary hypertension
I27.82	Chronic pulmonary embolism
I27.89	Other specified pulmonary heart diseases
I97.3	Postprocedural hypertension
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
P24.01	Meconium aspiration with respiratory symptoms
P28.5	Respiratory failure of newborn
P29.3	Persistent fetal circulation
P36.9	Bacterial sepsis of newborn, unspecified
P84	Other problems with newborn
Q33.1	Accessory lobe of lung
Q33.2	Sequestration of lung
Q33.3	Agenesis of lung
Q33.4	Congenital bronchiectasis
Q22.5	Ectopic tissue in lung
Q33.6	Congenital hypoplasia and dysplasia of lung
Q33.8	Other congenital malformations of lung
Q33.9	Congenital malformation of lung, unspecified
Q34.0	Anomaly of pleura
Q34.1	Congenital cyst of mediastinum
Q34.8	Other specified congenital malformations of respiratory system
Z98.89	Other specified postprocedural states

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC