Medica Central Coverage Policy

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Policy Name:	**Inhaled Nitric Oxide (iNO) Therapy MP9654**
Effective Date:	**12/01/2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Note: This policy does not address COVID-19 acute respiratory distress syndrome (ARDS). Requests will be considered on a case-by-case basis.

Inhaled nitric oxide therapy **COVERED** for the treatment of hypoxic respiratory failure in term and near-term (born at 34 or more weeks of gestation) neonates.

Inhaled nitric oxide therapy is investigative and unproven and therefore **NOT COVERED** for all other indications, including but not limited to:

1. Premature neonates (less than 34 weeks gestation)
2. Acute respiratory distress syndrome, pulmonary artery hypertension, and acute lung injury in adults
3. Acute hypoxemic respiratory failure in children
4. Prevention of ischemia-reperfusion injury/acute rejection following transplantation
5. Treatment of acute chest syndrome in persons with sickle cell disease
6. Post-operative management of pulmonary hypertension in infants and children with congenital heart disease
7. Treatment of persons with congenital diaphragmatic hernia.

There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

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Description

Nitric oxide (NO), a colorless, almost odorless gas, is naturally produced by various human tissues and is involved in numerous physiologic processes. When inhaled, NO selectively dilates the pulmonary vasculature, causing a decrease in pulmonary vascular resistance and a redistribution of blood flow to aerated lung regions. Therefore, inhaled nitric oxide (iNO) has been investigated for the treatment of various chronic and acute lung conditions as a technique to improve oxygenation in critically ill patients, both to reduce mortality and, in neonates, to reduce the need for extracorporeal membrane oxygenation (ECMO). Inhaled NO is provided through an NO delivery system used in conjunction with a ventilator or other breathing gas administration system.

FDA Approval

INOmax (INO Therapeutics, Clinton, NJ) was approved in by the FDA in 1999. INOmax is a vasodilator, which, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (> 34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for ECMO.

GeNOsyl (GeNO LLC, Waltham, MA) was granted orphan designation in 2012 for the treatment of persistent pulmonary hypertension in neonates.

Devices for delivery of NO are regulated by the FDA as Class II devices. Devices that have been cleared for marketing include the INOvent system for delivery of INOmax (1999), the AeroNOx delivery system (2000), the INOMAX DS (2006), intended for use in neonatal intensive care and neonate transfer settings, and the GeNOsyl MV-1000 (2012).

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

ICP Codes:

- **3E0F3SD** - Introduction of Nitric Oxide Gas into Respiratory Tract, Percutaneous Approach
- **3E0F7SD** - Introduction of Nitric Oxide Gas into Respiratory Tract, Via Natural or Artificial Opening
- **3E0F8SD** - Introduction of Nitric Oxide Gas into Respiratory Tract, Via Natural or Artificial Opening Endoscopic

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