Inhaled Nitric Oxide

Humana

Medicaid Medical Coverage Policy

Original Effective Date: 01/01/2025
Effective Date: 01/07/2026
Review Date: 09/02/2025
Policy Number: HUM-2236-001
Line of Business: Medicaid
State(s): VA

Table of Contents

Description

Inhaled nitric oxide (iNO) is a colorless, odorless gas used as a selective pulmonary vasodilator and administered through inhalation. US Food & Drug Administration (FDA) approved brands of nitric oxide include, but not limited to, **GENOSYL**, **INOmax** and **Noxivent** and are currently approved for the treatment of persistent pulmonary hypertension of the newborn (PPHN) to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO).

PPHN occurs after birth when there is increased pulmonary vascular resistance that causes right-to-left shunting of blood leading to severe hypoxemia. PPHN is often associated with pulmonary parenchymal abnormalities such as alveolar capillary dysplasia, lung hypoplasia, meconium aspiration, pneumonia and sepsis. In some neonates, there is no evidence of parenchymal disease and the cause is unknown.[4]

In acute vasoreactivity testing (VRT), iNO is intended to identify an individual who have pulmonary arterial hypertension (PAH) related to increased pulmonary vascular tone and are likely to respond to treatment using calcium channel blockers.[7]

Coverage Determination

Humana members may be eligible under the Plan for the administration of **iNO** for the following indications:

- Postoperative management of pulmonary hypertension in infants and children associated with congenital heart disease[6]; **OR**
- Vasoreactivity testing (VRT) in an adult to evaluate PAH to determine if the individual might benefit from calcium channel blocker therapy[7,14,20]; **OR**
- Term or near team infant (born at 34 weeks gestation or greater)[8,9] for the following indications:
    - Hypoxic respiratory failure associated with clinical or echocardiographic evidence of persistent pulmonary hypertension of the newborn (PPHN)[2,5,6,8,9,15]; **AND**
    - Failure, contradiction or intolerance of conventional therapy (eg, administration of high concentrations of oxygen, alkalizing agents, high frequency ventilation, hyperventilation, neuromuscular blockade, sedation, vasodilators)[11]; **AND**
    - Absence of congenital diaphragmatic hernia (CDH)[4,6,15,13]; **AND**
    - Maximum duration of treatment is 14 days or until oxygen desaturation has been resolved, whichever occurs first[6,9]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the **administration of iNO** for any indications other than those listed above. All other indications are considered not medically necessary.

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments

93463	Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

References

1. American Academy of Pediatrics (AAP). Clinical Report. Use of inhaled nitric oxide in preterm infants. https://aap.org. Published January 2014.

2. American Association for Respiratory Care (AARC). AARC Clinical Practice Guideline. Evidence-based clinical practice guideline: inhaled nitric oxide for neonates with acute hypoxic respiratory failure. https://aarc.org. Published December 2010.

3. American College of Chest Physicians. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and expert panel report. https://chestnet.org. Published March 2019.

4. American Heart Association (AHA). ACCF/AHA 2009 Expert consensus document on pulmonary hypertension. https://heart.org. Published April 28, 2009.

5. American Heart Association (AHA). Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. https://heart.org. Published November 24, 2015.

6. ClinicalKey. Drug Monograph. Nitric oxide. https://clinicalkey.com. Updated June 30, 2025.

7. ECRI Institute. Clinical Evidence Assessment. Inhaled nitric oxide for vasoreactivity and pulmonary hypertension treatment. https://home.ecri.org. Published March 8, 2005. Updated February 22, 2023.

8. ECRI Institute. Hotline Response. Inhaled prostacyclins as alternatives to nitric oxide for treating pulmonary hypertension in neonates and children. https://home.ecri.org. Published April 15, 2015.

9. ECRI Institute. Product Brief. INOmax inhaled nitric oxide (Mallinckrodt/INO Therapeutics LLC) for treating pulmonary hypertension in neonates. https://home.ecri.org. Published February 27, 2017.

10. Hayes, Inc. Health Technology Assessment. Inhaled nitric oxide for the treatment of respiratory failure in preterm newborns. https://evidence.hayesinc.com. Published November 6, 2018. Updated January 24, 2023.

11. Hayes, Inc. Medical Technology Directory. Inhaled nitric oxide for the treatment of persistent pulmonary hypertension in term and near-term newborns. https://evidence.hayesinc.com. Published January 15, 2009. Updated January 22, 2013.

12. UpToDate, Inc. Bronchopulmonary dysplasia (BPD): prevention. https://uptodate.com. Updated June 2025.

13. UpToDate, Inc. Congenital diaphragmatic hernia (CDH) in the neonate: management and outcome. https://uptodate.com. Updated June 2025.

14. UpToDate, Inc. Inhaled nitric oxide in adults: biology and indications for use. https://uptodate.com. Updated June 2025.

15. UpToDate, Inc. Meconium aspiration syndrome: management and outcome. https://uptodate.com. Updated June 2025.

16. UpToDate, Inc. Persistent pulmonary hypertension of the newborn (PPHN): management and outcome. https://uptodate.com. Updated June 2025.

17. UpToDate, Inc. Pulmonary hypertension due to lung disease and/or hypoxemia (group 3 pulmonary hypertension): treatment and prognosis. https://uptodate.com. Updated June 2025.

18. UpToDate, Inc. Pulmonary hypertension in children: management and prognosis. https://uptodate.com. Updated June 2025.

19. UpToDate, Inc. Respiratory distress syndrome (RDS) in preterm infants: management. https://uptodate.com. Updated June 2025.

20. UpToDate, Inc. Treatment of pulmonary arterial hypertension (group 1) in adults: pulmonary hypertension-specific therapy. https://uptodate.com. Updated June 2025.

21. US Food & Drug Administration (FDA). GENOSYL (nitric oxide), for inhalation use. https://fda.gov. Revised December 2019.

22. US Food & Drug Administration (FDA). INOMAX (nitric oxide) gas, for inhalation. https://fda.gov. Revised January 2023.

23. US Food & Drug Administration (FDA). Noxivent (nitric oxide) gas, for inhalation use. https://fda.gov. Revised August 2023.

24. US Food & Drug Administration (FDA). Ulspira (nitric oxide) gas, for inhalation use. https://fda.gov. Revised January 2, 2024.

Change Summary

01/01/2025 New Policy
09/02/2025 Annual Review, Coverage Change.