

Inhaled Nitric Oxide



Medicaid Medical Coverage Policy

Original Effective Date: 01/01/2025
Effective Date: 01/01/2025
Review Date: Click or tap to enter a date.
Policy Number: HUM-2236-000
Line of Business: Medicaid

Table of Contents

[Description](#)

[Coverage Limitations](#)

[References](#)

[Appendix](#)

[Coverage Determination](#)

[Coding Information](#)

[Change Summary](#)

Disclaimer

The Medical Coverage Policies are reviewed by the Humana Medicaid Coverage Policy Adoption (MCPA) Forum. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Inhaled nitric oxide (iNO) is a pulmonary vasodilator, used for the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN). 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.⁶

When nitric oxide is inhaled, pulmonary vasodilation occurs and an increase in the partial pressure of arterial oxygen results. Dilation of pulmonary vessels in well-ventilated lung areas redistributes blood flow away from lung areas where ventilation to perfusion ratios is poor. Examples of commercially available brands of nitric oxide include, but may not be limited to, GENOSYL, INOmax and Noxivent.

iNO is most often utilized in conjunction with ventilatory support to improve oxygenation and decrease the need for extracorporeal membrane oxygenation (ECMO). iNO may also be administered to infants and children for postoperative management of pulmonary hypertension. Another established use for iNO is with acute vasoreactivity testing for pulmonary arterial hypertension. It is performed during right heart catheterization procedures to determine how much the pulmonary blood vessels can relax over a period of time and help identify individuals who might respond favorably to calcium channel blockers.

Other proposed uses for iNO include, but may not be limited to, acute respiratory distress syndrome in adults, bronchopulmonary dysplasia or for treatment of pain related to sickle cell disease. **(Refer to Coverage Limitations section)**

Coverage Determination

Humana members may be eligible under the Plan for the use of iNO in a [neonate](#)* in conjunction with ventilatory support when the following criteria are met:

- Absence of congenital diaphragmatic hernia (CDH)^{4,15}; **AND**
- Conventional therapy has failed or is expected to fail (eg, administration of high concentrations of oxygen, alkalizing agents, high frequency ventilation, hyperventilation, neuromuscular blockade, sedation and vasodilators)¹⁵; **AND**
- Hypoxic respiratory failure¹² associated with clinical or echocardiographic evidence of persistent pulmonary hypertension of the newborn (PPHN); **AND**
- Maximum duration of treatment is 14 days or until oxygen desaturation has been resolved, whichever occurs first^{8,12}; **AND**
- Persistent pulmonary hypertension of the newborn (PPHN)^{7, 8,15,22}

Humana members may be eligible under the Plan for the use of iNO for postoperative management of pulmonary hypertension in infants and children with congenital heart disease.

Humana members may be eligible under the Plan for the use of iNO for acute vasoreactivity testing in pulmonary arterial hypertension.

***Neonate:** term or near term (born at 34 weeks or more) at birth through the first 28 days of life

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the use of iNO for any indications other than those listed above including, but not limited to:

- Acute respiratory distress syndrome (ARDS) in an adult^{8,14,16}; **OR**
- Acute vasoreactivity testing in an individual with pulmonary veno-occlusive disease (PVOD)²⁷; **OR**
- Bronchopulmonary dysplasia (BPD), also known as neonatal chronic lung disease (CLD)^{17,25}; **OR**
- Chronic obstructive pulmonary disease (COPD)²⁴; **OR**

- Dependent on right-to-left shunting of blood^{4,8}; **OR**
- Hepatopulmonary syndrome¹⁹; **OR**
- [Neonate](#)* less than 34 weeks gestation^{15,26}; **OR**
- Neonatal respiratory distress syndrome without PPHN^{8,15,22}; **OR**
- Prevention of primary graft dysfunction (PGD) following lung transplantation²³; **OR**
- Treatment of pain crisis in sickle cell disease⁸

These are considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

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://www.aap.org>. Published January 2014.
2. American Academy of Pediatrics (AAP). Off-label use of inhaled nitric oxide after release of NIH consensus statement. <https://www.aap.org>. Published April 2015.
3. American Academy of Pediatrics (AAP). Policy Statement. Use of inhaled nitric oxide. <https://www.aap.org>. Published August 2000. Updated December 2009.
4. 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://www.aarc.org>. Published December 2010.
5. American College of Chest Physicians. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and expert panel report. <https://www.chestnet.org>. Published March 2019.
6. American Heart Association (AHA). ACCF/AHA 2009 Expert consensus document on pulmonary hypertension. <https://www.heart.org>. Published April 28, 2009.
7. American Heart Association (AHA). Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. <https://www.heart.org>. Published November 24, 2015.
8. ClinicalKey. Drug Monograph. Nitric oxide. <https://www.clinicalkey.com>. Updated April 29, 2024.
9. Cochrane Library. Cochrane Database of Systematic Reviews. Inhaled nitric oxide for treating pain crises in people with sickle cell disease (review). <https://www.cochrane.org>. Published July 8, 2022.
10. ECRI Institute. Clinical Evidence Assessment. Inhaled nitric oxide for vasoreactivity and pulmonary hypertension treatment. <https://www.ecri.org>. Published March 8, 2005. Updated February 22, 2023.
11. ECRI Institute. Hotline Response. Inhaled prostacyclins as alternatives to nitric oxide for treating pulmonary hypertension in neonates and children. <https://www.ecri.org>. Published April 15, 2015.
12. ECRI Institute. Product Brief. INOmax inhaled nitric oxide (Mallinckrodt/INO Therapeutics LLC) for treating pulmonary hypertension in neonates. <https://www.ecri.org>. Published February 27, 2017.
13. 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.
14. Hayes, Inc. Health Technology Brief. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) in adults. <https://evidence.hayesinc.com>. Published March 31, 2014. Updated March 2, 2016.

15. 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.
16. UpToDate, Inc. Acute respiratory distress syndrome: fluid management, pharmacotherapy and supportive care in adults. <https://www.uptodate.com>. Updated July 2024.
17. UpToDate, Inc. Bronchopulmonary dysplasia: prevention. <https://www.uptodate.com>. Updated July 2024.
18. UpToDate, Inc. Congenital diaphragmatic hernia (CDH) in the neonate: management and outcome. <https://www.uptodate.com>. Updated July 2024.
19. UpToDate, Inc. Hepatopulmonary syndrome in adults: natural history, treatment, and outcomes. <https://www.uptodate.com>. Updated July 2024.
20. UpToDate, Inc. Inhaled nitric oxide in adults: biology and indications for use. <https://www.uptodate.com>. Updated July 2024.
21. UpToDate, Inc. Meconium aspiration syndrome: management and outcome. <https://www.uptodate.com>. Updated July 2024.
22. UpToDate, Inc. Persistent pulmonary hypertension of the newborn (PPHN): management and outcome. <https://www.uptodate.com>. Updated July 2024.
23. UpToDate, Inc. Primary lung graft dysfunction. <https://www.uptodate.com>. Updated July 2024.
24. UpToDate, Inc. Pulmonary hypertension due to lung disease and/or hypoxemia (group 3 pulmonary hypertension): treatment and prognosis. <https://www.uptodate.com>. Updated July 2024.
25. UpToDate, Inc. Pulmonary hypertension in children: management and prognosis. <https://www.uptodate.com>. Updated July 2024.
26. UpToDate, Inc. Respiratory distress syndrome (RDS) in preterm infants: management. <https://www.uptodate.com>. Updated July 2024.
27. UpToDate, Inc. Treatment and prognosis of pulmonary veno-occlusive disease/pulmonary capillary hemangiomatosis in adults. <https://www.uptodate.com>. Updated July 2024.
28. UpToDate, Inc. Treatment of pulmonary arterial hypertension (group 1) in adults: pulmonary hypertension-specific therapy. <https://www.uptodate.com>. Updated July 2024.

Change Summary

01/01/2025 New Policy.