Inhaled Nitric Oxide (iNO)

Lines of Business	*Document Type*
Commercial, Medicaid, Medicare	Policy
Who This Applies To	***States***
Health Services	Idaho, Montana, Oregon, Washington

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Nitric oxide is a colorless, slightly water-soluble gas that is produced through cellular metabolism. In the body, nitric oxide is involved in oxygen transport to the tissues, the transmission of nerve impulses and other physiological activities.

Inhaled nitric oxide (iNO) is a pulmonary vasodilator, proposed for the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension. When inhaled, pulmonary vasodilation occurs and an increase in the partial pressure of arterial oxygen results. Dilation of pulmonary vessels in well-ventilated lung areas redistribute blood flow away from lung areas where ventilation/perfusion ratios are poor.

Respiratory Failure is a clinical syndrome that is defined either by the inability to rid the body of carbon dioxide or establish an adequate blood oxygen level. Acute respiratory failure is a common problem seen in infants admitted to neonatal intensive care units. It is most often utilized in conjunction with ventilatory support in term or near-term neonates to improve oxygenation and decrease the need for extracorporeal membrane oxygenation (ECMO).

Criteria

Commercial

Inhaled Nitric Oxide (iNO) may be subject to post-service review.

I. Initiation of iNO Therapy

PacificSource considers initiation of inhaled nitric oxide (iNO) therapy medically necessary for the following:

A. Neonates (less than 14 days of chronological age and greater than or equal to 34 weeks gestational age at birth) who have **ALL** of the following:

1. Diagnosis of persistent primary pulmonary hypertension of the newborn (PPHN)
2. Hypoxic respiratory failure with documentation of contraindication, intolerance, or unsuccessful treatment of **ONE** of the following conventional therapies:
    - **a.** High concentration of oxygen (100%)
    - **b.** Induction of alkalosis
    - **c.** Neuromuscular blockade and sedation
    - **d.** Maximum respiratory support using conventional mechanical ventilation; **OR** high frequency oscillatory ventilation (HFOV)
3. Echocardiogram findings indicating **ALL** of the following:
    - **a.** Persistent primary pulmonary hypertension
    - **b.** Absence of congenital heart disease with right to left shunting
    - **c.** Absence of a congenital diaphragmatic hernia

B. Children (less than 18 years old and infants greater than or equal to 34 weeks gestational age at birth) when **ONE** of the following is met:

1. Congenital heart defect and **ONE** of the following:
    - **a.** iNO therapy for vasodilation is used in response to cardiac bypass surgery to repair a congenital heart defect that is causing Pulmonary Arterial Hypertension (PAH)
    - **b.** Perioperative stabilization and management of hypoxia
2. Pulmonary hypertensive crisis associated with heart or lung surgery
3. Rapid improvement of oxygenation is observed within 72 hours of iNO treatment

Note: If rapid improvement is not observed within 72 hours, then iNO treatment should be tapered off and further iNO treatments will be covered.

II. Continuation of Therapy

PacificSource considers inhaled nitric oxide (iNO) medically necessary for continuation of therapy when **ALL** of the following is met:

1. Previously met above initiation of iNO therapy criteria has been met

2. Continues to require iNO as evidenced by supplemental oxygen requirement to maintain oxygen saturations 80-100%
3. iNO is used less than or equal to 14 Days

Note: Medical Review is required for iNO for use less than or greater than 14 days.

Medicaid

PacificSource Community Solutions (PCS) follows the general coverage, limitations, and exclusions outlined in OARs 410-141-3820, 410-141-3825, and 410-120-1200. Relevant coverage guidance from the Health Evidence Review Commission (HERC) Prioritized List of Health Services; as well as any applicable Oregon Administrative Rules (OARs) may be used to determine coverage of Inhaled Nitric Oxide.

For diagnostic services not appearing on the Prioritized List, PCS utilizes the OHP's Diagnostic Procedure Code Group 1119 and covers these services when medically necessary and appropriate for the specific member as described in Covered Services OAR 410-141-3820. Services may be limited or excluded if the service meets the criteria outlined in OARs 410-141-3825 and 410-120-1200.

PacificSource Community Solutions (PCS) follows the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) coverage requirements in OAR 410-151-0000 through 410-151-0003 for EPSDT beneficiaries. Relevant coverage guidance, including but not limited to Guideline Note 94 and Ancillary Guideline A1, may be used to assist in informing a determination of medical necessity and medical appropriateness during the individual case review. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness as defined in OAR 410-151-0001 is required prior to denying. Refer to the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) policy for details..

Medicare

PacificSource Medicare follows Local Coverage Determination L37293 for Respiratory Care.

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow commercial criteria above for determination of coverage and medical necessity of initiation and continuation of Inhaled Nitric Oxide (iNO).

Experimental/Investigational/Unproven

PacificSource considers the following indications for treatment with Inhaled Nitric Oxide (iNO) to be experimental, investigational, or unproven:

- Neonates born less than 34 weeks gestation
- Neonates with congenital diaphragmatic hernia
- Acute respiratory distress syndrome (ARDS)
- Patients greater than 18 years old

Coding information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

93463 Pharmacologic agent administration (e.g., 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)

94002 Ventilation assist and management, initiation of pressure of volume present ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day

94003 Ventilation assist and management, initiation of pressure of volume present ventilators for assisted or controlled breathing; hospital inpatient/observation, hospital inpatient/observation, each subsequent day

94799 Unlisted pulmonary services or procedure

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Definitions

Alkalosis – A condition in which blood and body fluids pH is above normal range.

Arterial – Of or relating to one or more arteries or to the entire system of arteries.

Calcium Channel Blockers – Class of drugs that prevents the entry of calcium from entering cells of the heart and blood vessel walls, which allows the vessels to relax and widen, resulting in lower blood pressure.

Chronic Obstructive Pulmonary Disease (COPD) – Long term inflammatory lung disease that involves constriction of the airways and difficulty or discomfort in breathing.

Congenital – Existing at or dating from birth.

Dilation – To expand or cause to expand.

Extra Corporeal Membrane Oxygenation (ECMO) – Temporary mechanical support that oxygenates blood outside the body when the heart or lungs cannot adequately function.

Hyperventilation – A condition characterized by abnormally prolonged and rapid breathing, resulting in decreased carbon dioxide levels and increased oxygen levelsthat produce faintness, tingling of the fingers and toes and if continued, alkalosis and loss of consciousness.

Hypoxemic Respiratory Failure – Respiratory failure caused by inadequate oxygenation of the blood despite respiratory support.

Neonate – An infant in the first 28 days of life. For this policy, neonatal initiation criteria applies to infants who are less than 14 days of chronological age and at least 34 weeks' gestational age at birth.

Nitric Oxide – A colorless, slightly water-soluble gas that is produced through cellular metabolism. In the body, nitric oxide is involved in oxygen transport to thetissues, the transmission of nerve impulses and other physiological activities.

Perfusion – The pumping of a fluid through an organ or tissue.

Persistent Pulmonary Hypertension of the Newborn (PPHN) - Failure of normal circulatory transition after birth, resulting in elevated pulmonary vascular resistance, right-to-left shunting, and hypoxemia.

Pulmonary Hypertension –Elevated blood pressure in the pulmonary circulation.

Respiratory Failure – Inadequate gas exchange resulting in low blood oxygen, elevated carbon dioxide, or both.

Vasodilation – Dilation of the blood vessels, as by the action of a nerve.

Ventilatory – Relating to or serving for the provision of air to the respiratory system.

Related Policies

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Extracorporeal Membrane Oxygenation (ECMO)

Neonatal Intensive Care Unit (NICU) - DRG Validation

Unlisted, Unspecified, and Not Otherwise Specified Procedure Codes

References

American Academy of Pediatrics, Committee on Fetus and Newborn. (2014). Use of inhaled nitric oxide in preterm infants. Pediatrics, 133(1), 164–170. Reaffirmed August 2025. https://doi.org/10.1542/peds.2013-3444

Centers for Medicare & Medicaid Services. (2026). *Billing and coding: Respiratory therapy (respiratory care) (Article A56717).* https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56717

Children's Hospital of Philadelphia. (2025). Inhaled nitric oxide use in newborns with persistent pulmonary hypertension clinical pathway – N/IICU. https://www.chop.edu/clinical-pathway/nitric-oxide-inhaled-newborns-persistent-pulmonary-hypertension-niicu-clinical-pathway

Cookson, M. W., & Kinsella, J. P. (2024). Inhaled nitric oxide in neonatal pulmonary hypertension. Clinics in Perinatology, 51(1), 95–111. https://doi.org/10.1016/j.clp.2023.11.001

Finer, N. N., & Barrington, K. J. (2017). Nitric oxide for respiratory failure in infants born at or near term. Cochrane Database of Systematic Reviews, 2017(1), Article CD000399. https://www.cochrane.org/evidence/CD000399_nitric-oxide-respiratory-failure-infants-born-or-near-term

Fischer, H., Singh, T., Devlin, L., Obi, O., Robinson, T., Schultz, S., Telang, S., & Duncan, S. (2021). A quality improvement project improving the value of iNO utilization in preterm and term infants. Journal

of perinatology: official journal of the California Perinatal Association, 41(1), 164–172. Accessed 9/05/2023. https://doi.org/10.1038/s41372-020-0768-0

INO Therapeutics LLC. (2023). INOmax® (nitric oxide) gas, for inhalation: Prescribing information. https://www.inomax.com/downloads/Inomax-PI.pdf

Mitra, S., & Altit, G. (2023). Inhaled nitric oxide use in newborns. Pediatrics & Child Health, 28(2), 119–122. https://doi.org/10.1093/pch/pxac107

Oregon Health Authority. (n.d.). Oregon Administrative Rules (OARs): Chapter 410, Health Systems Division: Medical Assistance Programs. Oregon Secretary of State. https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87

Oregon Health Authority. (n.d.) Group 1119: Diagnostic Procedure Codes. Oregon Open Data Portal. https://data.oregon.gov/Health-Human-Services/Group-1119-Diagnostic-Procedure-Codes/74vi-r5ii/data_preview

symplr Evidence Analysis (formerly Hayes Knowledge Center). (January 24, 2023). Annual Review: Inhaled Nitric Oxide for the Treatment of Respiratory Failure in Preterm Newborns.

Appendix A. Document Control – *to update appendix fields, go to Properties Wizard*

Version 2 **of Doc #** 362

Policy Number: N/A

Effective Date: 09/17/2026

Next review: 11/17/2027

Original Creation Date: 02/08/2014

Date Archived: Not Archived Yet

Owner:

Business Owner: Health Services

Applicable regulation(s):

- OAR 410-120-1200 Excluded Services and Limitations
- OAR 410-141-3820 Covered Services
- OAR 410-141-3825 Excluded Services and Limitations
- OAR 410-151-0001 Definitions
- OAR 410-151-0002 Coverage Requirements

Policy Function: Posted to PacificSource.com - Clinical Policy

External entities affected: N/A

LOBO Committee Review completed: Committee Approval Date: 09/17/2026