Inhaled Nitric Oxide (iNO)

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *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 the term, near-term (born at 34 or more weeks of gestation), and pre-term (less than 34 weeks of gestation) 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 were greater than or equal to 34 weeks gestational age at birth) who have **ALL** of the following:
  1. Diagnosis of persistent primary pulmonary hypertension
  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 **ALL** 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 not 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 continued O2 requirement to maintain oxygen saturations 80-100%
3. iNO is used less than or equal to 14 Days

Medical Review is required for iNO for use less than or equal to 14 days.

Medicaid

PacificSource Community Solutions follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-120-1200 and 410-141-3820 through 3825, and Diagnostic Procedure Codes Group 1119 for coverage of Inhaled Nitric Oxide (iNO) for adult members 21 years and older.

PacificSource Community Solutions (PCS) follows EPSDT coverage requirements in OAR 410-151-0002 for members under the age of 21. Coverage of Inhaled Nitric Oxide (iNO) is determined through case-by-case reviews for EPSDT Medical Necessity and EPSDT Medical Appropriateness defined in OAR 410-151-0001.

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 internal policy for determination of coverage and medical necessity.

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

Definitions

Alkalosis – A condition of the blood and other body fluids in which the bicarbonate concentration is above normal. An imbalance in the pH of body fluids, in which the blood or other body tissue is more basic than normal.

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) – Utilized for individuals whose heart and lungs cannot normally function on their own. The individual's blood passes through a tube to the ECMO machine where it is oxygenated by an artificial lung and is returned to the body.

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

Hypoxemic Respiratory Failure – Occurs when there is an interference with normal gas exchange and causes lack of oxygen in the bloodstream, which affects the organs and tissues

Neonate – An infant in the first four weeks of life.

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 the tissues, the transmission of nerve impulses and other physiological activities.

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

Pulmonary Hypertension – Abnormally elevated blood pressure within the pulmonary circuit.

Respiratory Failure – A clinical syndrome that is defined either by the inability to rid the body of carbon dioxide or establish an adequate blood oxygen level.

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

Extracorporeal Membrane Oxygenation (ECMO)

Neonatal Levels of Care and Inpatient Management

References

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Appendix

Policy Number:

Effective: 11/1/2020 **Next review:** 11/1/2025

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): Oregon Administrative Rules (OAR) 410-120-1200, 410-141-3820,53835,OAR 410-151-0001, 410-151-0002.

Commercial Ops: 10/2024

Government Ops: 10/2024