Inhaled Nitric Oxide (iNO)

State(s):	LOB(s):
☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*	☒ *Commercial* ☒ *Medicare* ☒ *Medicaid*

Enterprise Policy

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. It is most often utilized in conjunction with ventilatory support in term or near-term (greater than 34 week's gestation) neonates to improve oxygenation and decrease the need for extracorporeal membrane oxygenation (ECMO). 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 redistributes 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 the most 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.

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:

A. Term and near-term (greater than 34 week's gestation) and less than 14 days of chronological age neonates who have persistent primary pulmonary hypertension and ALL of the following:

1. Hypoxic respiratory failure documentation of contraindication, intolerance, or unsuccessful treatment to conventional therapy as evidenced by at least **ONE** of the following:
    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).
2. Echocardiogram findings indicating **ALL** of the following:
    a. Diagnosis of PPHN;
    b. Absence of congenital heart disease with right to left shunting;
    c. Absence of a congenital diaphragmatic hernia;

B. Perioperative management in children up to age 18 years, and infants greater than or equal to 34 weeks gestational age at birth when **ALL** of the following

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

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 member has previously met initial approval criteria, **AND** meets **ALL** of the following:

1. Continues to require iNO as evidenced by a continued O2 requirement of 80-100%;
2. iNO is used less than or equal to 14 Days.

Medical Review is required for iNO for use greater than 14 days.

Contraindications:

Treatment with iNO is contraindicated in neonates with congenital heart disease dependent on right-to-left shunting of blood (e.g., patent ductus arteriosus (PDA)-dependent heart lesions).

Experimental/Investigational/Unproven

PacificSource considers the following indications for treatment with iNO to be experimental, investigational, or unproven:

- Neonates born less than 34 weeks gestation;
- Neonates with congenital diaphragmatic hernia;
- Acute respiratory distress syndrome (ARDS);
- Adults.

Medicaid

PacificSource Community Solutions follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-120-1200, 410-141-3820 to 3830, and Diagnostic Procedure Group 1119 of the OHP Prioritized List of Health Services for coverage of Inhaled Nitric Oxide (iNO).

Medicare

PacificSource Medicare follows this Policy and Procedure for coverage of Inhaled Nitric Oxide.

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

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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

Neonatal Levels of Care and Inpatient Management

References

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Appendix

Policy Number:

Effective: 11/1/2020 **Next review:** 10/1/2022

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): Oregon Administrative Rules (OAR) 410-120-1200, 410-141-3820 to 3830, and Diagnostic Procedure Group 1119 of the OHP Prioritized List of Health Services

Commercial Ops: 6/2022

Government Ops: 7/2022