# 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 determination 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

Inhaled Nitric Oxide (iNO) is a pulmonary vasodilator used in the treatment of neonatal hypoxic respiratory failure associated with pulmonary hypertension. It should reduce the need for extracorporeal membrane oxygenation (ECMO). The recommended starting dose is 20 ppm with continued use for 14 days or until improvement in the underlying disease process results in normal oxygen saturation. The dose is weaned incrementally, beginning as soon as four hours after the initiation of therapy, to 5 ppm before discontinuation. Doses above 20 ppm should not be used because of risk of methemoglobinemia and elevated nitrogen dioxide (NO2).

Commercial available brands of nitric oxide include, but may not be limited to: INOmax, Genosyl, and Noxivent. These are FDA approved for use in term or near term neonates with hypoxic respiratory failure associated with pulmonary hypertension and are off label for other uses.

## Criteria

**Policy applies to concurrent review and/or post service audit review.**

**Medical Review is required when criteria met but iNO used >14 days and/or if initial criteria guidelines not met.**

Inhaled nitric oxide (iNO) is medically necessary for initiation of therapy for:

A.)Term and near-term (>34 weeks gestation) and <14 days of chronological age neonates who have persistent primary pulmonary hypertension (PPHN) and ALL of the following:

a. Hypoxic respiratory failure with well documented contraindication, intolerance, or unsuccessful treatment to conventional therapy listed below:

i. High concentration of oxygen (100%)
ii. Induction of alkalosis
iii. Neuromuscular blockade and sedation
iv. Maximum respiratory support using conventional mechanical ventilation; **OR** high frequency oscillatory ventilation (HFOV)

b. Echocardiogram findings: **(ALL)**
i. Diagnosis of PPHN
ii. Absence of congenital heart disease with right to left shunting:
i. Patent ductus arteriosus (ODA) – dependent heart lesions
c. Absence of a congenital diaphragmatic hernia
d. Facility must have availability of extracorporeal membrane oxygenation (ECMO)
e. Facility must have personnel trained in the administration of inhaled nitric oxide

B.) Perioperative management in children up to age 18, and infants ≥ 34 weeks gestational age at birth, all of the following:
a. Congenital heart defect and one of the following:
i. iNO therapy for vasodilation is used in response to cardiac bypass surgery to repair a congenital heart defect that is causing PAH;
ii. Perioperative stabilization and management of hypoxia;
b. Pulmonary hypertensive crisis associated with heart or lung surgery
c. If no rapid improvement of oxygenation is observed within 72 hours then iNO treatment should be tapered off and further iNO treatments will not be covered.

**Continuation of Therapy:**

A.) Member has previously met initial approval criteria, and one of the following:
a. Continues to require iNO as evidenced by a continued O2 requirement of 80-100%;
b. When iNO is used >14 Days the request requires MD review

## Experimental/Investigational/Unproven

The following indication requires MD review for medical necessity

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

The following indications are considered investigational and not covered:
- Neonates born <34 weeks gestation
- Neonates with congenital diaphragmatic hernia
- Children up to age 18 who do not meet perioperative management criteria (B) above.
- Adults

### Medicaid

PacificSource Medicaid follows Oregon Health Plan (OHP) per Oregon Administrative Rules (OAR) 410-120-1200 and 410-141-3820 to 3825, 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.

**Covered when medically necessary when used in association with the administration of inhaled nitric oxide:**

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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## Appendix

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**Author(s):**

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