Inhaled Nitric Oxide

DRAFT

Humana

Medicaid Medical Coverage Policy

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Description

Inhaled nitric oxide (iNO) is a colorless, odorless gas used as a selective pulmonary vasodilator and administered through inhalation. US Food & Drug Administration (FDA) approved brands of nitric oxide include, but not limited to, GENOSYL, INOmax and Noxivent and are currently approved for the treatment of persistent pulmonary hypertension of the newborn (PPHN) to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO).

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]

In acute vasoreactivity testing (VRT), iNO is intended to identify an individual who have pulmonary arterial hypertension (PAH) related to increased pulmonary vascular tone and are likely to respond to treatment using calcium channel blockers.[10]

~~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 administration of **iNO** for the following indications:

- Postoperative management of pulmonary hypertension in infants and children **associated** with congenital heart disease[8]**; OR**

- Vasoreactivity testing **(VRT)** in an adult to evaluate PAH **to determine if the individual might benefit from calcium channel blocker therapy[10,20,28]; OR**

- **Term or near team infant (born at 34 weeks gestation or greater)[11,12]** for the following indications:

  - Hypoxic respiratory failure associated with clinical or echocardiographic evidence of persistent pulmonary hypertension of the newborn (PPHN)[4,7,8,11,12,15]; **AND**

  - **Failure, contradiction or intolerance of** 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**

  - Absence of congenital diaphragmatic hernia (CDH)[4,8,15,18]**; AND**

- Maximum duration of treatment is 14 days or until oxygen desaturation has been resolved, whichever occurs first[8,12]

~~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 failure[12] 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 administration of iNO for any indications other than those listed above. All other indications are considered not medically necessary.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

~~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 syndrome[19]; **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 transplantation[23]; **OR**~~
- ~~Treatment of pain crisis in sickle cell disease[8]~~

~~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

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32. **US Food & Drug Administration (FDA). Ulspira (nitric oxide) gas, for inhalation use. https://fda.gov. Revised January 2, 2024.**

Change Summary

01/01/2025 New Policy
09/02/2025 Annual Review, Coverage Change.