

# OH.CLI.1376 Inhaled Nitric Oxide

Effective Date:	January 12, 2024	Accountable Dept.:	Medicaid Clinical Delivery Experience 10585
Last Reviewed Date:	December 6, 2023		

Summary of Changes:

Humana Healthy Horizons™ in Ohio Inhaled Nitric Oxide policy H1376 underwent annual review, was updated, and placed on the new template. Added item #4 in the procedure section.

Scope:

This policy applies to all physical and behavioral health prior authorization requests received by Humana Healthy Horizons™ in Ohio.

Policy:

Humana Healthy Horizons™ in Ohio will use established criteria guidelines to make medical necessity decisions on a case-by-case basis, based on the information provided on the member’s health status.

For the following inhaled nitric oxide related CPT codes Humana Healthy Horizons™ in Ohio follows the below process.

Providers may submit authorization request(s) through the provider portal.

Providers may access physical and behavioral clinical coverage policies and medical necessity criteria at the below links.

Physical Health:

[www.humana.com/provider/medical-resources/ohio-medicaid/physical-health-clinical-coverage-policies](http://www.humana.com/provider/medical-resources/ohio-medicaid/physical-health-clinical-coverage-policies)

Behavioral Health:

[www.humana.com/provider/medical-resources/ohio-medicaid/behavioral-health-clinical-coverage-policies](http://www.humana.com/provider/medical-resources/ohio-medicaid/behavioral-health-clinical-coverage-policies)

Members may request a copy of the medical necessity criteria by calling member services at 877-856-5702 (TTY:711), Monday-Friday, 7AM to 8PM EST.

Providers may also request a copy of the medical necessity criteria by calling provider services at 877-856-5707 (TTY:711), Monday-Friday, 7AM to 8PM EST or emailing the request to [OHMCDUM@humana.com](mailto:OHMCDUM@humana.com).

## Description:

Inhaled Nitric Oxide	
CPT Code(s)	
<b>CPT Code(s) Summary</b>	93463
<b>CPT Code(s)</b>	<b>Description</b>
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)

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.

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 are 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 in term or near-term (at or greater than 34 weeks gestation) neonates (28 days of age or younger) 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)

## Procedures:

1. The Plan covers all benefits and services required in OAC chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.
2. When applying coverage policies and medical necessity criteria, the Plan will consider individual member needs and an assessment of the local delivery system.

3. The Plan uses the following hierarchy of guidelines to review for medical necessity:
  - 3.1 Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
  - 3.2 Nationally accepted evidence based clinical guidelines: MCG (formerly Milliman Care Guidelines), American Society of Addiction Medicine (ASAM) Level of Care Adolescent Guidelines and American Society of Addiction Medicine (ASAM) Patient Placement Criteria (ASAM Admission Guidelines).
  - 3.3 Humana Healthy Horizons™ in Ohio clinical policies
  - 3.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;
    - 3.4.1 Clinical practice guidelines and reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;
    - 3.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;
    - 3.4.3 Medical association publications;
    - 3.4.4 Government-funded or independent entities that assess and report on clinical care; Decision and technology such as Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
    - 3.4.5 Published expert opinions;
    - 3.4.6 Opinion of health professionals in the area of specialty involved;
    - 3.4.7 Opinion of attending provider;
  - 3.5 Dental: DentaQuest coverage guidelines and policies  
[Dental Coverage - Humana Healthy Horizons in Ohio | Humana](#)
  - 3.6 Vision: EyeMed coverage guidelines and policies  
[Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana](#)
4. When the plan receives a request for a primary code that requires a prior authorization, and the primary code is denied for lack of medical necessity, any related secondary codes submitted on the authorization request will be denied based on lack of medical necessity. When a primary code is approved, related secondary codes requiring prior authorization will be reviewed individually for medical necessity determination.

Only practitioners with the appropriate clinical expertise can make the decision to deny or reduce the amount, duration or scope of the services being requested.

Humana Healthy Horizons™ in Ohio requires prior authorization on all “Miscellaneous,” “Unlisted,” and “Not Otherwise Specified” codes. Medical necessity documentation and rationale must be submitted with the prior authorization request. The Medical Director adheres to the above process to align criteria based on the information provided on the member’s health status.

#### Coverage Determination Criteria:

Humana Healthy Horizons™ in Ohio members may be eligible under the Plan for the use of iNO in conjunction with ventilatory support when the following criteria are met:

- Neonate (28 days old or younger) at or greater than 34 weeks gestation; AND

- Failure of, contraindication or intolerance to conventional therapy (e.g., high concentrations of oxygen, high frequency ventilation, hyperventilation, induction of alkalosis, neuromuscular blockade and sedation); AND
- Hypoxic respiratory failure associated with clinical or echocardiographic evidence of PPHN; AND
- Maximum duration of treatment is 14 days or until oxygen desaturation has been resolved, whichever occurs first.

Humana Healthy Horizons™ in Ohio 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 Healthy Horizons™ in Ohio members may be eligible under the Plan for the use of iNO for acute vasoreactivity testing in pulmonary arterial hypertension.

#### Coverage Limitations:

Humana Healthy Horizons™ in Ohio 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 in an adult; OR
- Acute vasoreactivity testing in an individual with pulmonary veno-occlusive disease (PVOD); OR
- Bronchopulmonary dysplasia; OR
- Chronic obstructive pulmonary disease (COPD); OR
- Hepatopulmonary syndrome; OR
- Neonatal respiratory distress syndrome without PPHN; OR
- Neonate less than 34 weeks gestation; OR
- Neonate with unrepaired congenital diaphragmatic hernia (CDH); OR
- Prevention of primary graft dysfunction following lung transplantation; OR
- Treatment of pain crisis in sickle cell disease

This is 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.

#### Background:

Additional information about pulmonary hypertension may be found from the following websites:

- [American Heart Association](#)
- [American Lung Association](#)
- [National Heart, Lung and Blood Institute](#)
- [National Library of Medicine](#)

### Definitions:

1. Adverse Benefit Determination – As defined in OAC rule 5160-26-01, is a managed care entity's (MCEs):
  - (1) Denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit;
  - (2) Reduction, suspension, or termination of services prior to the member receiving the services previously authorized by the MCE;
  - (3) Failure to provide services in a timely manner as specified in rule 5160-26-03.1 of the Administrative Code;
  - (4) Failure to act within the resolution timeframes specified in rule 5160-26-08.4 of the Administrative Code;
  - (5) Denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable; or
  - (6) Denial, in whole or part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" as defined in 42 C.F.R. 447.45(b) (October 1, 2021) is not an adverse benefit determination)
2. American Society of Addiction Medicine (ASAM) – a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM produces a comprehensive set of standards for placement, continued stay, transfer or discharge of patients with addiction and co-occurring conditions used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
3. MCG® – are nationally recognized guidelines used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
4. Medically Necessary or Medical Necessity – Has the same meaning as OAC rule 5160-1-01:
  - A. Medical necessity for individuals covered by early and periodic screening, diagnosis, and treatment (EPSDT) is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability.
  - B. Medical necessity for individuals not covered by EPSDT is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability and without which the person can be expected to suffer prolonged, increased, or new morbidity; impairment of function; dysfunction of a body organ or part; or significant pain and discomfort.
  - C. Conditions of medical necessity for a procedure, item, or service are met all the following apply:
    - a. It meets generally accepted standards of medical practice;
    - b. It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
    - c. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
    - d. It is the lowest cost alternative that effectively addresses and treats the medical problem;

- e. It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
  - f. It is not provided primarily for the economic benefit of the provider nor for the sole convenience of the provider or anyone else other than the recipient.
- D. The fact that a physician, dentist, or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself make the procedure, item, or service medically necessary and does not guarantee payment.
- E. The definition and conditions of medical necessity articulated in this rule apply throughout the entire medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within the Ohio department of medicaid (ODM) coverage policies or rules.

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Version Control:

11/29/2023 - Humana Healthy Horizons™ in Ohio Inhaled Nitric Oxide policy H1376 underwent annual review, was updated, and placed on the new template. Added item #4 in the procedure section. - M. Joyce Medicaid Clinical Delivery Experience.