



**EXHALED NITRIC OXIDE AND BREATH  
CONDENSATE pH MEASUREMENT  
FOR RESPIRATORY DISORDERS  
HS-186**



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WellCare Health Insurance of Arizona, Inc.*

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**Exhaled Nitric Oxide and  
Breath Condensate pH  
Measurement for  
Respiratory Disorders**

**Policy Number: HS-186**

**Original Effective Date: 8/19/2010**

**Revised Date(s): 8/2/2011**

**DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## BACKGROUND

Chemiluminescence analyzers measure the concentration of nitric oxide (NO) in exhaled breath as a marker of airway inflammation. Specifically, the NIOX system uses a chemiluminescence gas analyzer that can measure low concentrations of NO. The device is calibrated between 0 and 200 parts per billion (ppb) for exhaled NO measurements, with an accuracy of  $\pm 2.5$  ppb or 5% (at 200 ppb). The ideal operating environment for NIOX includes an ambient temperature of 15° to 30°C, relative humidity of 30% to 7%, and atmospheric pressure of 860 hPa to 1060 hPa. The NIOX system can be used in an online and offline fashion. The patient exhales through a mouthpiece that is connected to the analyzer. A flow control system maintains exhalation at 50 mL per second, regardless of how forcefully a patient exhales. A visual display guides the patient to maintain an appropriate range of pressure while exhaling. According to the manufacturer, NIOX is suitable for children and adults,  $\geq 4$  years of age.

There was limited evidence from randomized, blinded, placebo-controlled studies that exhaled NO may be useful to guide inhaled steroid treatment in both adult and pediatric asthmatics, as well as predict inhaled steroid response. One study, in particular, reported a significantly lower inhaled steroid dose when monitored by exhaled NO compared with conventional tests. The difference, however, may be attributed to over-treatment in the control group, rather than more appropriate treatment in the exhaled NO group, since the dose was increased on the basis of five criteria compared with only exhaled NO. A well-designed study in pediatric patients reported that patients titrated with inhaled steroid doses based on symptoms alone had more significant bronchial hyperresponsiveness than patients titrated with inhaled steroid doses based on exhaled NO. However, investigators have criticized the use of hyperresponsiveness as a relevant study endpoint, indicating its limited clinical utility as an intermediate marker of asthma severity. There is limited evidence from a number of less rigorous studies, such as prospective observational and prospective controlled studies, to support the use of exhaled NO with the NIOX device to predict loss of asthma control after tapering or stopping the inhaled corticosteroid dose. However, these studies did not report whether it is possible to prevent relapses by adapting treatment based on exhaled NO levels. Additional studies are needed to assess whether effective control of airway inflammation provided by the NO breath test would have a significant effect on the natural history of asthma.

Evidence from the reviewed studies indicates that exhaled NO demonstrates moderate to good accuracy in diagnosing asthma and may be useful in predicting and monitoring inflammatory responses indicative of asthma exacerbation before and during anti-inflammatory treatment. There is also some evidence suggesting that exhaled NO may be useful for treatment management by dose titration to achieve optimal asthma control. However, the overall strength of the available evidence was moderate, with limitations in study design, small sample size, heterogeneous patient populations, variable methodological and treatment protocols, different outcome measures, and wide variations in threshold values of exhaled NO. There were no studies that evaluated whether exhaled NO resulted in improved long-term health outcomes, including effects on long-term asthma control, or improved quality of life. Additional studies are needed to clarify the role of exhaled NO breath testing in clinical practice (Hayes, 2007).

## POSITION STATEMENT

Measurement of exhaled nitric oxide **is considered experimental and investigational and NOT a covered benefit** in the diagnosis and monitoring of asthma and other respiratory disorders.

Measurement of exhaled breath condensate pH **is considered experimental and investigational and NOT a covered benefit** in the diagnosis and monitoring of asthma and other respiratory disorders.

Experimental, investigational or unproven and not covered when used to report measurement of exhaled nitric oxide or exhaled breath condensate.

## CODING

### Non-Covered CPT® Codes

- 83987** pH; exhaled breath condensate  
**94799** Unlisted pulmonary service or procedure when billed to report exhaled nitric oxide measurement  
**95012** Nitric oxide expired gas determination

**ICD-9-CM Procedure Code** - No applicable code

**HCPCS Level II Code** - No applicable code

### Non-Covered ICD-9-CM Diagnosis Codes

**493.00- 493.92** Asthma

**Not a covered benefit for all diagnosis.**

\*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.©©

## REFERENCES

### Peer Reviewed

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### Government Agencies, Professional and Medical Organizations

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## HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.