Medica Central Coverage Policy

Policy Name:	**Exhaled Breath Tests for Asthma and Other Inflammatory Pulmonary Conditions: Exhaled Nitric Oxide Breath Test and Exhaled Breath Condensate pH Measurement MP9560**
Effective Date:	**09/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Note: This policy is no longer scheduled for routine review of the scientific literature.

Exhaled nitric oxide breath tests are **COVERED** for the treatment of asthma when:

1. Used in the diagnosis of eosinophilic airway inflammation
2. Used in determining likelihood of steroid responsiveness in individuals with chronic symptoms suggestive of airway inflammation.

Exhaled nitric oxide breath tests are investigative and therefore **NOT COVERED** for all other inflammatory pulmonary indications, including but not limited to:

1. Chronic obstructive pulmonary disease (COPD)
2. Pulmonary hypertension
3. Cystic fibrosis
4. Allergic rhinitis/sinusitis
5. Nasal polyposis

Exhaled breath condensate pH measurements are investigative and therefore **NOT COVERED** for the treatment of asthma and other inflammatory pulmonary conditions. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

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Description

Exhaled Nitric Oxide: Nitric oxide is a gas produced throughout the body, including in the lungs, to fight inflammation and relax tight muscles. An exhaled nitric oxide test (fractional concentration of exhaled nitric oxide - FeNO) can assist with the diagnosis of and treatment of asthma. High levels of nitric oxide in the breath can mean the airways are inflamed, which is one sign of asthma. In an individual with asthma, this test is a way to determine how much lung inflammation is present and how well the inhaled steroids are suppressing the inflammation. This test is performed by using a portable device that measures the level of nitric oxide in the air that the individual slowly exhales through a mouthpiece into the measuring device.

Exhaled Breath Condensate pH: Measurements of exhaled breath condensate (EBC) markers are purported to be a non-invasive method for studying the composition of the fluid which lines the respiratory tract. One EBC marker currently under investigation is EBC pH. Researchers purport EBC pH values are lower in patients with inflammatory airway disorders, which include, but are not limited to, asthma, cystic fibrosis, chronic bronchitis, and bronchiectasis, than EBC pH values obtained from control subjects free of inflammatory pulmonary conditions.

Collection of a respiratory sample involves exhaling air through a mouthpiece into a cooling chamber that converts the sample into liquid droplets that can be analyzed.

FDA Approval

Exhaled Nitric Oxide: Multiple devices have received 510(k) clearance or FDA approval, including but not limited to:

1. NIOX MINO
2. Apieron Insight eNO System
3. NIOX VERO Airway Inflammation Monitor

Exhaled Breath Condensate pH: There are various systems for the collection of exhaled breath condensate listed with the FDA as Class I exempt devices. Two examples listed as a gas collection vessel, anesthesiology diagnostic devices, are the RTube™ (Respiratory Research, Inc.) and the ECoScreen/ECoScreen (Viasys® Healthcare).

Exempt Class I devices do not require a 510(k) premarket notification application and subsequent FDA clearance before marketing the device in the U.S. However, Class I devices are subject to the FDA's General Controls which include maintaining establishment registration standards, submitting a medical device listing, adhering to the Good Manufacturing Practices (GMP) guidelines, and labeling the device in according with FDA labeling regulations.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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CPT Codes:

Exhaled Nitric Oxide:

- **95012** - nitric oxide expired gas determination

Exhaled Breath Condensate pH:

- **83987** - pH; exhaled breath condensate

	Committee/Source	Date(s)
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