Medica 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

Current Policy Effective Date: 4/1/2016

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for 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 MinnesotaCare members, 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 about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

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

Coverage Policy

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.

Description

Exhaled Nitric Oxide: Nitric oxide (NO) is widespread in the human body and functions as a mediator in many metabolic activities, including the regulation of inflammation. In the lungs it serves as a bronchodilator. In tissue, NO is unstable and therefore difficult to measure. However, in gaseous form NO is relatively stable and measurement in exhaled air is possible. Recently, measurement of exhaled NO has gained attention as a purported adjunct to measurement and ongoing monitoring of asthma and other inflammatory pulmonary conditions. Nitric oxide concentration is expressed in parts per billion (ppb). In healthy adults exhaled NO ranges from 10 to 20 ppb, whereas exhaled NO ranges from 25 to 80 ppb in individuals with asthma. Also, exhaled NO values are higher
during an acute asthmatic exacerbation compared to patients in remission and are also higher in individuals with poor asthmatic control compared to those whose asthma is under control.

In the United States, exhaled NO is most commonly measured using chemiluminescence after reaction with ozone and is routinely measured during single breath exhalations. First, the patient inspires nitric oxide-free air to total lung capacity and then immediately exhales through a mouthpiece into the measuring device. The following areas of diagnosis and management of asthma and other inflammatory pulmonary conditions have been proposed for the clinical application of exhaled NO measurements: diagnosis/assessment of other conditions (including asthma, cystic fibrosis, COPD, rhinitis, primary ciliary dyskinesia, and chronic cough); response to anti-inflammatory treatment; monitoring treatment compliance; detection of steroid resistance; dose optimization; and prediction of exacerbations.

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. One commercially available system for breath condensate pH measurement for patients with pulmonary conditions is the RTube™ system. The RTube system consists of a disposable polypropylene condensation chamber that is cooled by an aluminum cooling sleeve which overlays the collection chamber. The test chamber can be sent to a reference laboratory where the pH is assayed using Argon deaeration. The results are recorded, tabulated, interpreted and returned to the sender.

FDA Approval

Exhaled Nitric Oxide: The NIOX® Nitric Oxide Test System (Aerocrine Inc.) is currently the only FDA approved exhaled NO device. The system was granted 510(k) clearance in May 2003. The device tests nitric oxide using a chemiluminescence gas analyzer with integrated software. The device is not intended for infants, for children less than four years of age, or for patients who fail to cooperate with the necessary requirements of test performance. The NIOX system is not recommended for use in critical care, emergency care, or anesthesiology. The Breathmeter™ (Ekips Technologies, Inc.) is another device that measures exhaled NO. This device uses tunable-diode laser absorption spectroscopy. To date, the Breathmeter has not received FDA approval for marketing in the United States.

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 accordance 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.

CPT Codes:
Exhaled Nitric Oxide:
• 95012 - nitric oxide expired gas determination

Exhaled Breath Condensate pH:
• 83987 - pH; exhaled breath condensate

Original Effective Date: 5/1/2007
Re-Review Date(s): 2/15/2010
9/19/2012
1/20/2016