Medical Coverage Policy

Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders

☐ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☒ Test ☐ Other

Effective Date: 8/1/2009  Policy Last Updated: 2/21/2011

☐ Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

☒ Prospective review is not required.

Description:
Existing techniques for monitoring the status of underlying inflammation in individuals with asthma have focused on bronchoscopy (with lavage and biopsy) or analysis by induced sputum. Given the cumbersome nature of these techniques, the ongoing assessment of asthma focuses not on the status of the underlying chronic inflammation, but rather on regular assessments of respiratory parameters such as FEV-1 (forced expiratory volume in one second) and peak flow. Therefore, there has been interest in non-invasive techniques to assess the underlying causes of chronic inflammation as is reflected by measurements of inflammatory mediators. Two new strategies have been investigated, the measurement of exhaled nitric oxide and the evaluation of exhaled breath condensate.

Measurement of Nitric Oxide
The most commonly used technique for measurement of exhaled nitric oxide is chemiluminescence after reaction with ozone. Exhaled nitric oxide is typically measured during single breath exhalations. First, the subject inspires nitric oxide-free air via a mouthpiece until total lung capacity is achieved, followed immediately by exhalation through the mouthpiece into the measuring device. The early studies of exhaled nitric oxide showed various levels of nitric oxide in health and disease, attributed to the lack of a standardized technique of measurement. In 1999, the American Thoracic Society published recommendations for the standardized measurement of exhaled nitric oxide.

There are currently two devices that measure exhaled nitric oxide. The FDA approved Nitric Oxide Monitoring System (NIOX) which evaluates an asthma patient's response to anti-inflammatory therapy and the Breathmeter used to measure exhaled nitric oxide using laser spectroscopy. The Breathmeter has not yet received FDA approval for marketing.

Collection and Measurement of Exhaled Breath Condensate (EBC)
The basic technique of collecting EBC consists of a technique to cool exhaled air and collect EBC droplets. One commercially available system, the RTube consists of a disposable polypropylene condensation chamber that is cooled by an overlying aluminum cooling sleeve. There are a variety of laboratory techniques to measure the components of EBC, including such simple techniques as pH measurement, to the more sophisticated gas chromatography/mass spectrometry or high performance liquid chromatography, depending on the component of interest.
Analysis of exhaled nitric oxide has been proposed as a marker of inflammation that could be useful in monitoring disease activity and directing treatment in patients with asthma. Exhaled nitric oxide levels have been shown to be elevated in patients with asthma, to be higher during periods of acute exacerbation, and to correlate with other measures of inflammation. There is insufficient evidence in the published medical literature, however, to demonstrate the clinical utility of this procedure. Available evidence does not demonstrate that the addition of exhaled nitric oxide measurement results in improved clinical outcomes for patients with asthma when compared to conventionally managed patients.

Analysis of pH and other markers in exhaled breath concentrate (EBC) has also been proposed as a non-invasive method of sampling airway secretions and measuring airway inflammation in patients with asthma and other chronic pulmonary diseases. Although a non-invasive method of determining inflammation would be useful in monitoring disease activity and directing treatment, well-designed controlled trials are needed in order to establish the clinical utility of this technique.

Medical Criteria:
Measurement of exhaled or nasal nitric oxide, or collection and analysis of exhaled breath condensate is considered **not medically necessary** in the diagnosis and management of asthma and other respiratory disorders because there is insufficient evidence in the published medical literature to demonstrate its efficacy.

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Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable not medically necessary benefits/coverage.

Coding:
The following CPT codes are considered **not medically necessary**:

83987
95012

Published:
- Provider Update, May 2009
- Provider Update, May 2010
- Provider Update, May 2011
- Provider Update, May 2012

References:


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