Medical Coverage Policy | Exhaled Nitric Oxide Monitoring

EFFECTIVE DATE: 08|01|2009
POLICY LAST UPDATED: 03|19|2014

OVERVIEW
Current techniques for diagnosing and monitoring asthma and predicting exacerbations are suboptimal. Two new strategies, evaluation of exhaled nitric oxide (NO) and exhaled breath condensate are proposed. There are commercially available devices for measuring NO in expired breath and various laboratory techniques for evaluating components of exhaled breath condensate.

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
Blue CHiP for Medicare and Commercial
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.

MEDICAL CRITERIA
Not applicable.

BACKGROUND
The 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. Potential uses in management of asthma include assessing response to anti-inflammatory treatment, monitoring compliance with treatment, and predicting exacerbations.

Measurement of Exhaled Nitric Oxide
Nitric Oxide (NO) is an important endogenous messenger and inflammatory mediator that is widespread in the human body, functioning, for example, to regulate peripheral blood flow, platelet function, immune reactions, and neurotransmission and to mediate inflammation. While the role of NO in asthma pathogenesis is still under investigation, patients with asthma have been found to have high levels of exhaled NO, which decreases with treatment with corticosteroids. In biologic tissues, NO is unstable, limiting measurement. However, in the gas phase, NO is fairly stable, permitting its measurement in exhaled air. Exhaled NO is typically measured during single breath exhalations. First, the subject inspires NO-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 a 2009 joint statement by the American Thoracic Society (ATS) and European Respiratory Society (ERS), there is a consensus of the recommendations for the standardized measurement of exhaled nitric oxide.

Several devices measuring exhaled NO are commercially available in the United States. In 2003, the U.S. Food and Drug Administration (FDA) cleared for marketing the Nitric Oxide Monitoring System (NIOX®), with the indication that measurements of the fractional nitric oxide (NO) concentration in expired breath (FE-NO)] provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments in asthma. In March 2008, the NIOX MINO was cleared for marketing. The main differences between this new device and the NIOX are that the NIOX MINO is handheld and portable and that it is not suitable for children younger than age 7 years.

Measurement of Exhaled Breath Condensate
Exhaled breath condensate (EBC) consists of exhaled air passed through a condensing or cooling apparatus, resulting in an accumulation of fluid. Although EBC is primarily derived from water vapor, it also contains aerosol particles or respiratory fluid droplets, which in turn contain various nonvolatile inflammatory mediators, such as cytokines, leukotrienes, oxidants, antioxidants, and various other markers of oxidative stress. 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.

The RTube™ Exhaled Breath Condensate collection system (Respiratory Research Inc.) and the ECoScreen EBC collection system (CareFusion, Germany) are registered with FDA as a Class I devices that collect expired gas. Respiratory Research has a proprietary gas-standardized pH assay, which, when performed by the company, is considered a laboratory-developed test.

Measurement of exhaled nitric oxide and exhaled breath condensate are considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the service is effective.

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 for BlueCHiP for Medicare and Commercial:**

83987, 95012

RELATED POLICIES
Not applicable.

PUBLISHED

Provider Update	Jun 2014
Provider Update	Jun 2013
Provider Update	May 2012
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3. See KC, Christiani DC. Normal values and thresholds for the clinical interpretation of exhaled nitric oxide levels in the US general population: results from the National Health and Nutrition Examination Survey 2007-2010. Chest 2013; 143(1):107-16.

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