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 (EBC) are proposed. These techniques are also potentially useful in the management of other conditions such as chronic obstructive pulmonary disease and chronic cough. There are commercially available devices for measuring NO in expired breath and various laboratory techniques for evaluating components of EBC.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Measurement of exhaled nitric oxide and exhaled breath condensate is considered not medically necessary in the diagnosis and management of asthma and other respiratory disorders including, but not limited to, chronic obstructive pulmonary disease and chronic cough because the evidence is insufficient to determine the effect of the technology on health outcomes.

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

BACKGROUND
®), with the indication that measurements of the fractional 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. NIOX cannot be used with infants or children approximately under the age of 4, as measurement requires patient cooperation. 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 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 the FDA as 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.

For individuals who have suspected asthma or suspected eosinophilic asthma who receive measurement of fractional exhaled nitric oxide (FeNO), the evidence includes multiple retrospective and prospective studies of diagnostic accuracy, along with systematic reviews of those studies. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, morbid events, and functional outcomes. There is a large volume of reports on the sensitivity and specificity of FeNO in asthma diagnosis. The available evidence is limited by variability in FeNO cutoff levels used to diagnose asthma, and by variability in sensitivity and specificity for asthma diagnosis. The accuracy of the cutoffs recommended by the American Thoracic Society guidelines has not been evaluated in the diagnosis of asthma. Also, no studies were identified that evaluated whether the use of FeNO improved the accuracy of asthma diagnosis compared with clinical diagnosis. For the use of FeNO in the diagnosis of eosinophilic asthma, using the criterion standard of sputum eosinophilia, the diagnostic accuracy is moderate. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have asthma who receive medication management directed by FeNO, the evidence includes multiple randomized controlled trials and systematic reviews of those trials. Relevant outcomes are symptoms, change in disease status, morbid events, and functional outcomes. The available randomized controlled trials evaluating the use of FeNO tests for the management of patients have not consistently found improvement in health outcomes. Two Cochrane reviews from 2016, one on adults and the other on children, found FeNO-guided asthma management reduced the number of individuals who had more than 1 exacerbation, but had no impact on day-to-day symptoms. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have suspected or confirmed respiratory disorders other than asthma who receive measurement of FeNO, the evidence includes a crossover trial and observational studies. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, morbid events, and functional outcomes. The available evidence assessing the use of FeNO for respiratory disorders other than asthma is limited by heterogeneity in the conditions evaluated and uncertainty about the potential clinical use. The evidence is insufficient to determine the effect of the technology on health outcomes.

For individuals who have suspected or confirmed respiratory disorders who receive measurement of EBC, the evidence includes observational studies reporting on the association between various EBC components and disease severity. Relevant outcomes are test accuracy and validity, symptoms, change in disease status, morbid events, and functional outcomes. There is considerable variability in the particular EBC components measured and criteria for standardized measurements. Also, there is limited evidence on the use of EBC for determining asthma severity, diagnosing other respiratory conditions, or guiding treatment decisions for asthma or other respiratory conditions. The evidence is insufficient to determine the effect of the technology on health outcomes.

**CODING**

**BlueCHIP for Medicare and Commercial Products**

The following CPT codes are considered not medically necessary:

83987  pH; exhaled breath condensate

95012  Nitric oxide expired gas determination

**RELATED POLICIES**

Not applicable

**PUBLISHED**

500 EXCHANGE STREET, PROVIDENCE, RI 02903-2699
(401) 274-4848  WWW.BCBSRI.COM

MEDICAL COVERAGE POLICY | 2
REFERENCES
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