

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>12-7-11</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>101-224</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Tech</i> <i>* Also enclosed are 4 booklet</i> <i>cleaned 12/21/11, letter attached.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>12-10-11</i> <input type="checkbox"/> FOIA DATE DUE _____ <input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			



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December 2, 2011

DEC 02 2011

VED

Anthony E. Keck, M.P.H.
Medical Director
Department of Health and Human Services
1801 Main Street
Columbia, SC 29201

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Dear Mr. Keck,

I am writing on behalf of the Medical University of South Carolina regarding coverage and reimbursement for exhaled nitric oxide (FeNO) measurement. Currently exhaled nitric oxide measurement described by CPT 95012 is not included on the Medicaid Fee Schedule. I am requesting that the Department of Health and Human Services update the fee schedule to provide coverage and reimbursement of exhaled nitric oxide testing when it is considered medically necessary for asthma patients.

The American Thoracic Society (ATS) recently published an official Practice Guideline for the Interpretation of Exhaled Nitric Oxide Levels for Clinical Applications. The evidence-based guideline provides recommendations for clinicians regarding the use and interpretation of FeNO measurements in clinical practice. The ATS is widely recognized as the governing body to establish the latest standards of care for adult and pediatric respiratory disease. The American Thoracic Society strongly recommends the use of exhaled nitric oxide measurement for the following applications.

- Diagnosis of eosinophilic airway inflammation
- Determine the likelihood of steroid responsiveness in individuals with chronic respiratory symptoms possibly due to airway inflammation
- Monitor airway inflammation in asthma patients

In addition, the ATS guideline defines the cut points to be used in the interpretation of FeNO measurement:

- High FeNO greater than 50 ppb (>35 ppb in children) be used to indicate that eosinophilic inflammation and, in symptomatic patients, responsiveness to corticosteroids are likely.
- Low FeNO less than 25 ppb (<20 ppb in children) be used to indicate that eosinophilic inflammation and responsiveness to corticosteroids are less likely.

I have enclosed the ATS guideline for your review, demonstrating that FeNO has become a standard of good practice for physicians that treat asthma patients. Also enclosed for your consideration is a clinical dossier regarding FeNO and the management of patients with asthma. Substantial clinical utility and validity of exhaled nitric oxide has been presented in peer-reviewed literature.



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In addition, I am enclosing a peer-reviewed paper regarding asthma in pregnancy that was published in the September 2011 issue of *Lancet*. This paper concludes that asthma exacerbations during pregnancy can be significantly reduced with a validated FeNO-based treatment algorithm.

The measurement of exhaled nitric oxide is the only clinical test for measuring airway inflammation that can be performed consistently and accurately in clinical practice at the point-of-care. The test is easy to administer and not effort dependent hence it is a more reproducible test for young children.

Exhaled nitric oxide measurement is universally covered and reimbursed by all Medicare contractors (\$20.73 national average payment) and is included on the Medicaid Fee Schedule in 28 states and the District of Columbia.

Further, the Agency for Healthcare Research and Quality (AHRQ) has recognized the *Urban Health Plan Asthma Relief Street* program as an innovative program that improves health care quality and reduces disparities. The program supports community-based organizations that serve low-income, at-risk populations in the New York City area. The Asthma Relief Street program provides comprehensive, standardized asthma management at 12 health centers. All patients are evaluated for asthma, with those already diagnosed with asthma being assessed at every primary care visit and those not previously diagnosed being screened twice per year. Children age 6 and older receive an exhaled nitric oxide test. A physician evaluates the FeNO test results as a part of the screening and intake process. The program has increased the number of people diagnosed with and treated for asthma, reduced asthma hospitalizations among children, and generated significant cost savings. See <http://www.innovations.ahrq.gov> for more information.

I urge you to consider updating your Medicaid Fee Schedule and provide coverage and reimbursement of exhaled nitric oxide measurement by adding CPT 95012 to the Fee Schedule on or before January 1, 2012. Exhaled nitric oxide measurement should be covered as a non-invasive, inexpensive, cost-effective technology for detection of airway inflammation to be used in the management of asthma patients.

Please feel free to contact me at (843)792-3712 if you have questions or require additional information. I would happy to meet with you in person or by phone to discuss the benefits of the exhaled nitric oxide technology. I look forward to working with you and South Carolina Medicaid to provide quality asthma care to your beneficiaries.

Best regards,

Sonia N. Bains, M.D.
Assistant Professor
Department of Pulmonary, Critical Care, Allergy & Sleep Medicine
Medical University of South Carolina

Enclosures

AMERICAN JOURNAL OF



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VOLUME 184
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SEPTEMBER 1 2011
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An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (F_{ENO}) for Clinical Applications

Raed A. Dweik, Peter B. Boggs, Serpil C. Erzurum,
Charles G. Irvin, Margaret W. Leigh, Jon O. Lundberg,
Anna-Carin Olin, Alan L. Plummer and D. Robin Taylor,
on Behalf of the American Thoracic Society Committee on
Interpretation of Exhaled Nitric Oxide Levels (F_{ENO}) for
Clinical Applications

THE LANCET

www.thelancet.com

Reprint

† Management of asthma in pregnancy guided by measurement of fraction of exhaled nitric oxide: a double-blind, randomised controlled trial

Heather Powell, Vanessa E Murphy, D Robin Taylor, Michael J Hensley, Kirsten McCaffery, Warwick Giles, Vicki L Clifton, Peter G Gibson
Lancet 2011; 378: 983-9

Personalised medicine for asthma management in pregnancy

Stanley J Szefler
Lancet 2011; 378: 963-4



**Consensus Statement on
The Use of Fractional Exhaled Nitric Oxide (FE_{N₂O})
in the Clinical Management of Asthma**

National Jewish Health | December 2009



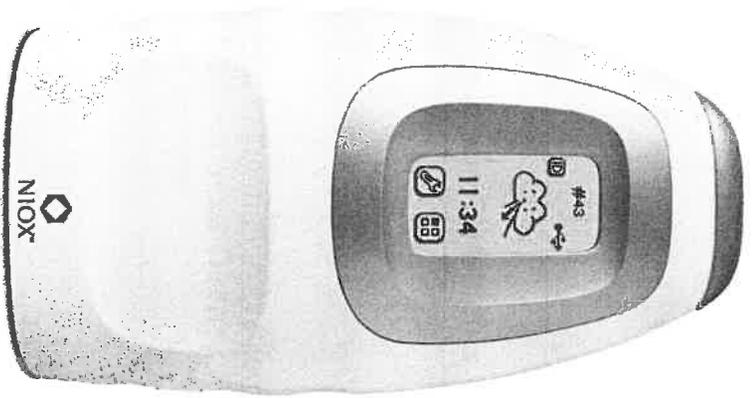
**National Jewish
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Clinical Dossier

FENO [exhaled nitric oxide] & the management of patients with asthma



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL



TO <i>Grise Williams</i>	DATE <i>12-7-11</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>101264</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____		
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Teck</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>12-16-11</i> DATE DUE _____		
<i>* Also enclosed are 4 bottles</i>		<input type="checkbox"/> Necessary Action	

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. <i>Hal Williams</i>	<i>12-19-11</i>		
2. <i>BS Jones</i>	<i>12-21-11</i> <i>12-21-11</i>		
3.			
4.			



December 21, 2011

Sonia N. Bains, M.D.
Assistant Professor, MUSC
8992 University Boulevard, Suite 200
North Charleston, South Carolina 29406

Dear Dr. Bains:

Thank you for your letter regarding the request that the South Carolina Department of Health and Human Services (SCDHHS) update the fee schedule to include the coverage and reimbursement of exhaled nitric oxide testing. We welcome the opportunity to be of assistance.

The Medical Director at SCDHHS has reviewed your request, and has deemed this procedure appropriate when clinically indicated to manage a patient's asthma. We have taken the necessary steps to update our system to reimburse for this procedure.

Thank you for bringing your concern to our attention and for your continued participation in the South Carolina Healthy Connections Medicaid program. If you have any questions please contact Mr. William Feagin, Division Director of Policy and Program Administration, in the Office of Physicians, Pharmacy, and Enhanced Care Services at (803) 898-2660.

Sincerely,

Melanie "BZ" Giese, RN
Deputy Director

MG/ws