MEDICAL POLICY

SUBJECT: BRONCHIAL THERMOPLASTY
POLICY NUMBER: 7.01.88
CATEGORY: Technology Assessment

EFFECTIVE DATE: 02/20/14
REVISED DATE: 01/22/15, 03/15/16

• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
Based upon our review and assessment of the peer-reviewed literature, bronchial thermoplasty has not been medically proven to be effective and therefore is considered investigational for all indications, including but not limited to, the treatment of asthma.

POLICY GUIDELINES:
The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:
Asthma is a chronic inflammatory disorder of the airways characterized by recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. The current management of asthma consists of environmental control, patient education, management of co-morbidities, and regular follow-up for all affected individuals, as well as a stepped approach to medication treatment. Despite this multidimensional approach, many patients continue to experience considerable morbidity. In addition to ongoing efforts to optimally implement standard approaches to asthma treatment, new therapies are being developed.

One new therapy is bronchial thermoplasty, the controlled delivery of radiofrequency energy to heat tissues in the distal airways. Bronchial thermoplasty is based on the premise that patients with asthma have an increased amount of smooth muscle in the airway and that contraction of this smooth muscle is a major cause of airway constriction. The thermal energy delivered via bronchial thermoplasty aims to reduce the amount of smooth muscle and thereby decrease muscle-mediated bronchoconstriction with the ultimate goal of reducing asthma-related morbidity. Bronchial thermoplasty is intended as a supplemental treatment for patients with severe persistent asthma and are performed on an outpatient basis, and each session lasts approximately 1 hour. During the procedure, a standard flexible bronchoscope is placed through the patient’s mouth or nose into the most distal targeted airway and a catheter is inserted into the working channel of the bronchoscope. After placement, the electrode array in the top of the catheter is expanded, and radiofrequency energy is delivered from a proprietary controller and used to heat tissue to 65 degrees Centigrade over a 5-mm area. The positioning of the catheter and application of thermal energy is repeated several times in contiguous areas along the accessible length of the airway. At the end of the treatment session, the catheter and bronchoscope are removed. A course of treatment consists of 3 separate procedures in different regions of the lung scheduled about 3 weeks apart.

RATIONALE:
In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, Inc., Sunnyvale, CA now part of Boston Scientific Corporation) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with inhaled corticosteroids and long-acting beta antagonists or LABAs. Use of the treatment is contraindicated in patients with implantable devices and those with sensitivities to lidocaine, atropine or benzodiazepines. It should also not be used while patients are experiencing an asthma exacerbation, active respiratory infection, bleeding disorder, or within 2 weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty.
The largest RCT with the most rigorous methodology investigating bronchial thermoplasty was the AIR2 trial (M Castro, et al. 2010 and 2011). This was the only published trial that was double-blind and sham-controlled, and also the only published RCT with sites in the United States. Over one year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome, mean change in quality-of-life score, but was found to be superior on a related outcome, improvement in quality of life of at least 0.5 points on the Asthma Quality of Life Questionnaire (AQLQ) scale. There was a high rate of response in the sham group of the AIR2 trial, which suggests a large placebo effect, particularly for subjective outcomes such as quality of life. On the secondary outcomes, bronchial thermoplasty provided greater benefit than sham treatment on some, but not all, of the outcomes. In the AIR trial (G Cox, et al. 2007, Thomson, et al. 2011) and RISA trial (ID Pavord, et al. 2007 and 2013) there were improvements in quality of life for the bronchial thermoplasty group. However, given the lack of benefit in the AIR2 trial, it is possible that the differences in quality of life for these other trials were due to placebo effect.

**CODES:**

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<tr>
<th>Number</th>
<th>Description</th>
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<tr>
<td>31660</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with bronchial thermoplasty, 1 lobe</td>
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<tr>
<td>31661</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with bronchial thermoplasty, 2 or more lobes</td>
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Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

**CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates. Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

**REFERENCES:**


* key article

KEY WORDS:
Alair System, Asthma, Bronchial thermoplasty

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based upon our review, bronchial thermoplasty is not addressed in National or regional CMS coverage determinations or policies.