# MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|---|---|
| **Medical Policy Title** | **BRONCHIAL THERMOPLASTY** |
| **Policy Number** | **7.01.88** |
| **Category** | **Technology Assessment** |
| **Effective Date** | **02/20/14** |
| **Revised Date** | **01/22/15, 03/17/16, 03/16/17, 01/18/18, 01/17/19, 01/16/20** |
| **Product Disclaimer** | • *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*<br>• *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*<br>• *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* |

## 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 is performed on an outpatient basis. Each session lasts approximately one 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 three separate procedures in different regions of the lung, scheduled about three 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 two 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-blinded 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.

The BCBSA TEC assessment (March 2015) concluded the following: There is a sizeable population with severe persistent asthma that could be considered for BT. Evidence from the three trials of BT applicable to individuals with severe, persistent, and inadequately controlled asthma—a single trial incorporated a sham control—is accompanied by uncertainty concerning the net health outcome. For FDA approval, superiority with respect to the primary outcomes (albeit changed in AIR2) must be considered together with safety. To judge impact on the net health outcome requires considering a set of informative health outcomes, including asthma control and exacerbations, QOL, ICS and LABA use, and lung function (primarily for safety). The substantial response observed following a sham procedure in AIR2 emphasizes the necessity of a sham control to estimate treatment effects. Although a number of outcomes in the AIR2 trial favored BT, others did not, and for those that did, effect magnitudes could be interpreted as modest. BT is accompanied by a risk of adverse events during the treatment phase that may require hospitalization—a tradeoff for potential future benefit. Although under conditions of controlled trials and careful patient selection, the morbidity from adverse events was not described as concerning, adoption outside those settings, where patient selection may be less strict and providers less experienced with the device, could be accompanied by a different adverse event profile. There is very little published evidence obtained outside the investigational setting on potential harms and benefit.

## CODES

- *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).*

**CPT Codes**

| Code | Description |
|---|---|
| 31660 **(E/I)** | Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with bronchial thermoplasty, 1 lobe |

| Code | Description |
|---|---|
| 31661 **(E/I)** | Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with bronchial thermoplasty, 2 or more lobes |



**HCPCS Codes**

| Code | Description |
|---|---|
| C9751 | Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s) (effective 1/1/2019) |

**ICD10 Codes**

| Code | Description |
|---|---|
| Investigational for all diagnoses | |

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*Key Article

## KEY WORDS

Alair System, Asthma, Bronchial thermoplasty

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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