

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Bronchial Thermoplasty
Policy Number	7.01.88
Category	Technology Assessment
Original Effective Date	02/20/14
Committee Approval Date	01/22/15, 03/17/16, 03/16/17, 01/18/18, 01/17/19, 01/21/21, 12/16/21
Current Effective Date	03/23/23
Archived Date	03/24/22
Archive Review Date	03/23/23
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

Based upon our criteria 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.

*Refer to Corporate Medical Policy # 11.01.03 Experimental and Investigational Services*

## 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 multi-dimensional approach, many patients continue to experience considerable morbidity. In addition to ongoing efforts optimally to implement standard approaches to asthma treatment, new therapies are being developed.

One therapy is bronchial thermoplasty (BT), the controlled delivery of radiofrequency energy to heat tissues in the distal airways. BT is based on the premise that patients with asthma have an increased amount of airway smooth muscle (ASM) mass and that contraction of this smooth muscle is a major cause of airway constriction. The thermal energy delivered via BT aims to reduce the ASM and, thereby, decrease muscle-mediated bronchoconstriction, with the ultimate goal of reducing asthma-related morbidity. BT is intended as a supplemental treatment for patients with severe, persistent asthma. It is performed on an outpatient basis, and 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, then 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.

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### 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 (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 BT.

BT is included as a consideration in step 5 of the Global Initiative for Asthma (GINA) guidelines/stepwise approach to care, for patients who are severe asthmatics, when treatment is refractory to medium-to-high dose inhaled corticosteroids with a LABA or controller such as tiotropium, a leukotriene modifier, or theophylline. However, the GINA guidelines do specify that the evidence for efficacy and long-term safety is limited.

The largest randomized, controlled trial (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 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 (I.D. 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

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

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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 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)
0781T (E/I)	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi ( <i>effective 01/01/2023</i> )
0782T (E/I)	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus ( <i>effective 01/01/2023</i> )

**ICD10 Codes**

Code	Description
	Investigational for all diagnoses

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\*Key Article

### **KEY WORDS**

Alair System, Asthma, Bronchial thermoplasty

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, bronchial thermoplasty is not addressed in National or Regional Medicare coverage determinations or policies.