MEDICAL POLICY

Medical Policy Title	**Bronchial Thermoplasty**
Policy Number	**07.01.88**
Current Effective Date	March 20, 2025
Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Bronchial thermoplasty is considered **investigational** for all indications, including but not limited to, the treatment of asthma.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

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 that is 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.

SUPPORTIVE LITERATURE

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 the period of one-year, BT 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.

Leroux and Colleagues (2024) aimed to evaluate the effects of BT for patients with severe uncontrolled asthma with frequent exacerbations in a randomized, single-blind clinical trial. The study included individuals with asthma with a minimum of four severe exacerbations within the last year. Individuals were randomized to a BT (n=15) interventional or control (n=15) group. Individuals completed four follow up visits corresponding to three, six, nine, and 12 months after the last procedure for the BT group. The primary outcome was the number of exacerbations at 15 months after inclusion, or 12 months after BT. In total, patients in the BT group experienced less severe exacerbations than the control group (6.09 [95 % confidence interval [CI], 4.95−7.50] compared to 8.28 (CI95, 6.89 −9.96]) which was equivalent to a 27 % reduction in the BT group by the end of the 15 month study period. Despite the positive outcomes, there were several limitations to the study, including its small sample size, an unclear understanding of the impact that corticosteroid treatments utilized during thermoplasty procedures would have on the results, and a risk for bias given the control group did not undergo an endoscopic procedure. The authors concluded that a large multicenter study that includes patients with the most severe forms of asthma is needed.

PROFESSIONAL GUIDELINE(S)

Global Initiative for Asthma (GINA) Guidelines (2024), given the small number of studies with limitations, includes the following guidance regarding bronchial thermoplasty:

"Bronchial thermoplasty is a potential treatment option at Step 5 in some countries for adult patients whose asthma remains uncontrolled despite optimized therapeutic regimens and referral to an asthma specialty center (Evidence B)…However, there is a need for longer-term follow up of larger

cohorts comparing effectiveness and safety, including for lung function, in both active and sham-treated patients."

REGULATORY STATUS

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.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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

HCPCS Codes

Code	Description
C9751 (E/I)	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)

Code	Description
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
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

ICD10 Codes

Code	Description
Investigational for all Diagnoses	

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SEARCH TERMS

Alair System, Asthma, Bronchial thermoplasty

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- 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.
- 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.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

01/22/15, 03/17/16, 03/16/17, 01/18/18, 01/17/19, 01/21/21, 12/16/21, 03/24/22, 03/23/23, 03/21/24, 03/20/25

Date	Summary of Changes
03/20/25	• Annual Review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
02/20/14	• Original effective date