

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
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • 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 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.

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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 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.

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 3 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
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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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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

REFERENCES

American College of Chest Surgeons. Position statement for coverage and payment for bronchial thermoplasty. 2014 May [http://www.chestnet.org/News/CHEST-News/2014/05/Position-Statement-for-Coverage-and-Payment-for-Bronchial-Thermoplasty] accessed 12/3/18.

Bicknell S, et al. Effectiveness of bronchial thermoplasty in severe asthma in ‘real life’ patients compared with those recruited to clinical trials in the same centre. Ther Adv Respir Dis 2015 Dec;9(6):267-71.

Blaiss MS, et al. guiding principles for use of newer biologics and bronchial thermoplasty for patients with severe asthma. Ann Allergy Asthma Immunol 2017 Dec;119(6):553-540.

BlueCross BlueShield Association. Bronchial thermoplasty. Medical Policy Reference Manual Policy #7.01.127. 2018 Jun 14.

BlueCross BlueShield Association. Technology Evaluation Center (TEC) Assessment Program. Bronchial thermoplasty for treatment of inadequately controlled severe asthma. 2015 Mar;29(2).

Burn J, et al. procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics. J Asthma 2017 Oct;54(8):872-879.

*Castro M, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. Am J Respir Crit Care Med 2010 Jan 15;181(2):116-24.

*Castro M, et al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Ann Allergy Asthma Immunol 2011 Jul;107(1):65-70.

Chung KF, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J 2014 Feb;43(2):343-73.

Chung KF. Managing severe asthma in adults: lessons from the ERS/ATS guidelines. Curr Opin Pulm Med 2015 Jan;21(1):8-15.

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Chupp G, et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicenter studies. Eur Respir J 2017 Aug 31;50(2).

*Cox G, et al. Asthma control during the year after bronchial thermoplasty. N Engl J Med 2007 Mar 29;356(13):1327-37.

*Cox G, et al. Bronchial thermoplasty for severe asthma. Curr Opin Pulm Med 2011 Jan;17(1):34-8.

D'Anchi KE, et al. Effectiveness and safety of bronchial thermoplasty in management of asthma. Comparative Effectiveness Review No. 202. [<https://doi.org/10.23970/AHRQEPCCER202>] accessed 12/6/18.

Du Rand IA, et al. Summary of the British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax 2011 Nov;66(11):1014-15.

Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. 2014 May . Updated 2018. [<https://ginasthma.org/2018-gina-report-global-strategy-for-asthma-management-and-prevention/>] accessed 12/3/18.

Iyer VN, et al. bronchial thermoplasty: reappraising the evidence (or lack thereof). Chest 2014 Jul;146(1):17-21.

Kheir F and Majid A. Bronchial thermoplasty: a nonpharmacologic therapy for severe asthma. Clin Chest Med 2018;39(1):261-269.

Kirby M, et al. Bronchial thermoplasty in asthma: 2-year follow-up using optical coherence tomography. Eur Respir J 2015 Sep;46(3):859-62.

Kondapaneni M, et al. Impact of bronchial thermoplasty on the FeNO levels in asthmatic patients. Chest 2013 Oct 1;144(4 meeting abstracts):796A.

Langton D, et al. Bronchial thermoplasty in severe asthma in Australia. Intern Med J 2017 May;47(5):536-541.

Laxmanan B, et al. Advances in bronchial thermoplasty. Chest 2016 Sept;150(3):694-704.

National Institute for Health and Clinical Excellence. Bronchial thermoplasty for severe asthma. IPG 419. 2012 Jan 2012 [<http://www.nice.org.uk/nicemedia/live/12774/57927/57927.pdf>] accessed 12/7/17.

National Institute for health and Care Excellence. Alair bronchial thermoplasty system for adults with severe difficult to control asthma. Medtech innovation briefing 2016 July 11. [nice.org.uk/guidance/mib71].

Niven RM, et al. Indirect comparison of bronchial thermoplasty versus omalizumab for uncontrolled severe asthma. J Asthma 2017 July 14: 1-9. [Epub ahead of print].

*Pavord ID, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. Am J Respir Crit Care Med 2007 Dec 15;176(12):1185-91.

Pavord ID, et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. Ann Allergy Asthma Immunol 2013 Nov;111(5):402-7.

Pretolani M, et al. Effectiveness of bronchial thermoplasty in patients with severe refractory asthma: clinical and histopathologic correlations. J Allergy Clin Immunol 2017 April;139(4):1176-1185.

*Thomson NC, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. BMC Pulm Med 2011 Feb 11;11:8.

Thomson NC, et al. Bronchial thermoplasty for severe asthma. Curr Opin Allergy Clin Immunol 2012 Jun;12(3):241-8.

Torrego A, et al. Bronchial thermoplasty for moderate or severe persistent asthma in adults. Cochrane Database Syst Rev 2014 March 3:CD009910.

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Wechsler ME, et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. J Allergy Clin Immunol 2013 Dec;132(6):1295-1302.

Wilhelm CP, et al. Bronchial thermoplasty: a review of the evidence. Ann Allergy Asthma Immunol 2016 Feb;116(2):92-98.

*Wu Q, et al. meta-analysis of the efficacy and safety of bronchial thermoplasty in patients with moderate-to-severe persistent asthma. J Int Med Res 2011;39(1):10-22.

Zafari Z, et al. Cost-effectiveness of bronchial thermoplasty, Omalizumab, and standard therapy for moderate-to-severe allergic asthma. PLoS one 2016 Jan 11(1):e0146003.

Zein JG, et al. Cost effectiveness of bronchial thermoplasty in patients with severe uncontrolled asthma. J Asthma 2016;53(2):194-200.

Zhou JP, et al. Long-term efficacy and safety of bronchial thermoplasty in patients with moderate-to-severe persistent asthma: a systematic review and meta-analysis. J Asthma 2016;53(1):94-100.

*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.