

Corporate Medical Policy

Bronchial Thermoplasty

File Name:	bronchial_thermoplasty
Origination:	10/2010
Last CAP Review:	3/2012
Next CAP Review:	3/2013
Last Review:	3/2012

Description of Procedure or Service

Bronchial thermoplasty is a newly available potential treatment option for patients with severe persistent asthma. It consists of radiofrequency energy delivered to the distal airways with the aim of decreasing smooth muscle mass believed to be associated with airway inflammation.

Background

Asthma, a chronic lung disease, affects approximately 7% of adults and 9% of children in the United States and, in 2006, accounted for approximately 440,000 hospitalizations and 3600 deaths. (1) Asthma symptoms include episodic shortness of breath that is generally associated with other symptoms such as wheezing, coughing and chest tightness. Objective clinical features include bronchial hyper-responsiveness and airway inflammation, and reversible airflow obstruction (at least 12% improvement in forced expiratory volume in 1 second [FEV-1] post-bronchodilator, with a minimum of 200 ml improvement). However, there is substantial heterogeneity in the inflammatory features of patients who are diagnosed with asthma and this biological diversity is responsible, at least in part, for the variable response to treatment in the asthma population.

Management of asthma consists of environmental control, patient education, management of comorbidities and regular follow-up for all affected individuals, as well as a stepped approach to medication treatment. Guidelines from the National Heart, Lung and Blood Institute (NHLBI) define 6 pharmacologic steps: step 1 for intermittent asthma, and steps 2-6 for persistent asthma. (2) The preferred daily medications: step 1: short-acting beta-agonists as needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting beta-agonists (LABA) or medium-dose ICS; step 4: medium dose ICS and LABA; step 5: high-dose ICS and LABA; and, step 6: high-dose ICS and LABA, and oral corticosteroids.

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 (i.e., steps 5 and 6 in the stepwise approach to care).

Bronchial thermoplasty procedures are performed on an outpatient basis and last approximately one hour each. 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

Bronchial Thermoplasty

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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Bronchial thermoplasty for the treatment of asthma is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Bronchial Thermoplasty is covered

Not applicable.

When Bronchial Thermoplasty is not covered

Bronchial thermoplasty for the treatment of asthma is considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

In April 2010, the Alair Bronchial Thermoplasty System (Asthmatx, Inc., Sunnyvale, CA) was approved by the 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 LABAs. (3) 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.

An updated literature review through May 2011 was completed using MEDLINE. Three RCTs on bronchial thermoplasty have been published; only one of these, the AIR2 trial, had sites in the United States. AIR2 was also the only published trial that was double-blind and sham-controlled. The high rate of response in the sham group of the AIR2 suggests a large placebo effect with novel asthma treatments, particularly for subjective outcomes such as quality of life; this calls into question conclusions about efficacy in the earlier trials that did not have a sham control. In the AIR2 trial, bronchial thermoplasty provided benefit in terms of quality of life and some, but not all, secondary outcomes. It is unclear, however, which patients are most likely to respond. Data from the AIR2 suggests that those with more severe asthma may experience the greatest improvement. Also of concern, there are insufficient safety data; no published safety data beyond 1 year have been published and the potential long-term adverse effects of bronchial thermoplasty are not known. Additional randomized trials using sham controls are needed to confirm the findings of the AIR2 study. In addition, long-term follow-up is needed to understand potential adverse complications.

Bronchial Thermoplasty

Long-term safety data up to five years are available from the participants in the AIR trial and do not suggest a high rate of delayed complications following bronchial thermoplasty. However, long-term safety data are not yet available from the two other RCTs and long-term data on clinical outcomes such as exacerbation rates and quality of life are not available. Clinical trials are underway to study the long-term safety of the Alair device in participants in the RISA and AIR2 trial, and the AIR2 trial is evaluating long-term efficacy for up to five years. Other ongoing trials are evaluating safety of the Alair device in a United States setting and predictors of response to treatment.

Since the impact of this procedure on net health outcome is uncertain, this technology is considered investigational.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0276T, 0277T, 31899, C1886

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 6/10/2010

Food and Drug Administration News Release. April 27, 2010. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm209909.htm> . July 2010.

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

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

Castro M, Rubin AS, Laviolette 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; 181(2):116-24.

Medical Director Review 10/2010.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 7/14/2011

Specialty Matched Consultant Advisory Panel 3/2012

Policy Implementation/Update Information

11/9/10 New medical policy issued. Bronchial thermoplasty for the treatment of asthma is considered investigational. Notification given 11/9/10. Effective date 2/15/11. Reviewed with Medical Director 10/2010. (1r)

10/11/11 Added HCPCS codes C9730 and C9731 for effective date 7/1/2011 to the billing/coding

Bronchial Thermoplasty

- section. Also added CPT codes 0276T and 0277T to the billing/coding section for effective date January 1, 2012. No change in policy statement. Reference added. (lpr)
- 11/22/11 Deleted HCPCS codes C9730 and C9731 from the Billing/Coding section for 2012. (lpr)
- 1/1/2012 Added HCPCS code C1886 to Billing/Coding section for effective date 1/1/2012. (lpr)
- 3/30/12 Specialty Matched Consultant Advisory Panel review meeting 3/21/2012. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.