

Corporate Medical Policy

Bronchial Thermoplasty

File Name:	bronchial_thermoplasty
Origination:	10/2010
Last CAP Review:	3/2020
Next CAP Review:	3/2021
Last Review:	3/2020

Description of Procedure or Service

Bronchial thermoplasty is a 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 8.3% of adults and 8.3% of children in the U. S. and, in 2017, accounted for approximately 1.7 million emergency department visits and 3615 deaths. 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 hyperresponsiveness, airway inflammation, and reversible airflow obstruction (at least 12% improvement in forced expiratory volume in 1-second post-bronchodilator, with a minimum of 200 mL improvement). However, there is substantial heterogeneity in the inflammatory features of patients diagnosed with asthma, and this biologic 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 co-morbidities 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. 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

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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.

Regulatory Status

In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, Sunnyvale, CA, now part of Boston Scientific) was approved by the U.S. Food and Drug Administration through the premarket approval process for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with low-dose inhaled corticosteroids and long-acting β -agonists. 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.

******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**.

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Policy Guidelines

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes three randomized controlled trials (RCTs) and observational studies. The relevant outcomes are symptoms, quality of life (QOL), hospitalizations, and treatment-related morbidity. Early studies (RISA, AIR) investigated safety outcomes, finding similar rates of adverse events and exacerbations between the bronchial thermoplasty and control groups. These trials were limited by their lack of sham control. The AIR2 trial is the largest of the three published RCTs, and the only one double-blinded and sham-controlled, with sites in the U. S. Over one year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome of mean change in the QOL score but was found to

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be superior on a related outcome, improvement in the QOL of at least 0.5 points on the Asthma Quality of Life Questionnaire. There was a high response rate in the sham group of the AIR2 trial, suggesting a large placebo effect, particularly for subjective outcomes such as QOL. There are no long-term sham-controlled efficacy data. Findings on adverse events from the three trials have suggested that bronchial thermoplasty is associated with a relatively high rate of adverse events, including hospitalizations during the treatment period, but not in the posttreatment period. Safety data up to five years have been reported in the RCTs for patients treated with bronchial thermoplasty but not for control patients. Safety data from a U.K. registry study, published in 2016, found that 20% of bronchial thermoplasty procedures were associated with a safety event (ie, procedural complications, emergency respiratory readmissions, emergency department visits, and/or postprocedure overnight stays). Conclusions cannot be drawn about the effect of bronchial thermoplasty on the net health outcome due to the limited amount of sham-controlled data (one RCT) on short-term efficacy, the uncertain degree of treatment benefit in that single sham-controlled trial, the lack of long-term sham-controlled data in the face of a high initial placebo response, and the presence of substantial adverse events. Also, there is a lack of data on patient selection factors for this procedure and, as a result, it is not possible to determine whether there are patient subgroups that might benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

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: 31660, 31661, 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

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 7/12/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 11/8/12

Specialty Matched Consultant Advisory Panel 3/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 7/11/13

Specialty Matched Consultant Advisory Panel 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 7/10/14

Specialty Matched Consultant Advisory Panel 3/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 7/9/15

Specialty Matched Consultant Advisory Panel 3/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 6/16/16

Specialty Matched Consultant Advisory Panel 3/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 6/8/17

Specialty Matched Consultant Advisory Panel 3/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 6/14/18

Specialty Matched Consultant Advisory Panel 3/2019

National Institute for Health and Care Excellence. Bronchial thermoplasty for severe asthma. Interventional procedures guidance. <https://www.nice.org.uk/guidance/ipg635>. Assessed April 12, 2019

Global Initiative for Asthma. Asthma Management and Prevention for Adults and Children Older than 5 Years. <https://ginasthma.org/wp-content/uploads/2019/04/GINA-2019-main-Pocket-Guide-wms.pdf>. Assessed April 12, 2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.127, 6/13/19

Specialty Matched Consultant Advisory Panel 3/2020

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. (lr)

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

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- 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)
- 11/13/12 Reference update. No change to policy statement. (lpr)
- 12/28/12 Added CPT codes 31660 and 31661 to the Billing/Coding section and deleted CPT codes 0276T and 0277T for effective date 1/1/2013. (lpr)
- 4/16/13 Description section updated. Specialty Matched Consultant Advisory panel review meeting 3/20/13. Reference updated. No change to policy statement. (lpr)
- 8/13/13 Description section updated. Reference updated. No change to policy statement. (lpr)
- 5/13/14 Specialty Matched Consultant advisory panel meeting 4/30/2014. No change to policy statement. (lpr)
- 7/1/14 Prior review is required. Sr. Medical Director review 6/2014. Notification given 7/1/14 for effective date 9/30/14. (lpr)
- 9/30/14 Reference updated. (lpr)
- 4/28/15 Specialty Matched Consultant Advisory panel review 3/25/2015. No change to policy statement. (lpr)
- 9/1/15 Reference added. No change to policy statement. (lpr)
- 4/29/16 Specialty Matched Consultant Advisory Panel review 3/30/2016. No change to policy intent. (lpr)
- 7/26/16 Reference added. No change to policy statement. (lpr)
- 4/28/17 Revised Policy Guidelines section and placed Regulatory Status under Description section. No change to policy intent. Specialty Matched Consultant Advisory Panel review 3/29/2017. (lpr)
- 7/28/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)
- 7/27/18 Reference added. (lpr)
- 4/30/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. No change to policy statement. (lpr)
- 4/28/20 Description, Policy Guidelines and References updated. Specialty Matched Consultant Advisory Panel review 3/31/2020. No change to policy statement. (eel)

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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.