



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Bronchial Thermoplasty

Policy #: 434
Category: Surgery

Latest Review Date: June 2021
Policy Grade: A

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **bronchial thermoplasty** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

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.

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 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 six pharmacologic steps: Step 1 for intermittent asthma and Steps 2 through 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. A focused update in 2020 addressed the use of add-on long-acting antimuscarinic agents (LAMA), immunotherapy, and bronchial thermoplasty (see Practice Guidelines and Position Statements).

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 recently developed 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 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 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°Celsius 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.

KEY POINTS:

The policy was created with a literature review through May 7, 2021.

Summary of Evidence

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes 3 RCTs and observational studies. Relevant outcomes are symptoms, 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 3 published RCTs, and the only 1 double-blinded and sham-controlled, with sites in the U. S. Over 1 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 be superior on a related outcome, improvement in the QOL of at least 0.5 points on the AQLQ. 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 limited long-term sham-controlled efficacy data. Findings on adverse events from the 3 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 10 years have been reported for patients in the AIR2 trial, with a higher rate of new cases of bronchiectasis observed in bronchial thermoplasty-treated patients. Data from a U.K. registry showed 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), with uncertain benefit. Conclusions cannot be drawn about the effect of bronchial thermoplasty on the net health outcome due to the limited amount of

sham-controlled data (1 RCT) on short-term efficacy, the uncertain degree of treatment benefit in that single sham-controlled trial, the lack of sufficient 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 that the technology results in an improvement in the net health outcome.

There was a high response rate in the sham group of the AIR2 trial, which suggests 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 the 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 (i.e., procedural complications, emergency respiratory readmissions, emergency department visits, and/or postprocedure overnight stays), with uncertain benefit.

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. In addition, 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.

Practice Guidelines and Position Statements

Global Initiative for Asthma (GINA)

Global Initiative for Asthma is an international network of organizations and professionals with expertise in asthma. The group has been updating a report entitled Global Strategy for Asthma Management and Prevention annually since 2002; the most recent update was issued in 2021. The organization has recommended stepped care for treatment of asthma. Step 5 options for patients with uncontrolled symptoms and/or exacerbations include referral for phenotypic investigation and potential add-on treatment. Add-on treatments may include long-acting muscarinic antagonists, biologics (eg, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab), and systemic corticosteroids.

A guide for the diagnosis and management of difficult-to-treat and severe asthma was published in 2019. For patients whose asthma remains uncontrolled despite GINA step 4 or 5 treatment with no evidence of type 2 inflammation (ie, medium- or high-dose inhaled corticosteroids and long-acting beta-agonists), treatment options include a trial of tiotropium or macrolide if not already tried, low-dose oral corticosteroids, and consideration of bronchial thermoplasty with registry enrollment. Bronchial thermoplasty with registry enrollment may also be considered for

patients who do not respond to type 2-targeted biologic therapy. The guidance notes that the evidence for the efficacy and long-term safety of bronchial thermoplasty is limited.

American College of Chest Physicians (ACCP)

In May 2014, ACCP posted a position statement on coverage and payment for bronchial thermoplasty. The document states in part,

“...CHEST believes that based on the strength of the clinical evidence, bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental. Randomized controlled clinical trials of bronchial thermoplasty for severe asthma have shown a reduction in the rate of severe exacerbations, emergency department visits, and days lost from school or work. Additionally, data published in December, 2013 demonstrates the persistence of the reduction in asthma symptoms achieved by bronchial thermoplasty for at least five years...”

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2018) published guidance on bronchial thermoplasty for severe asthma. The guidance stated: "Current evidence on the safety and efficacy on bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." It was also noted that "further research should report details of patient selection and long-term safety and efficacy outcomes."

National Asthma Education and Prevention Program

In 2020, the National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) Expert Panel Working Group published focused updates to the National Heart, Lung, and Blood Institute's guidelines for the diagnosis and management of asthma. This update was based on prior systematic reviews of the evidence published by the Agency for Healthcare Research and Quality.

The following conditional recommendation based on low certainty evidence on the use of bronchial thermoplasty was issued:

- "In individuals ages 18 years and older with persistent asthma, the Expert Panel conditionally recommends against bronchial thermoplasty.
- Individuals ages 18 years and older with persistent asthma who place a low value on harms (short-term worsening symptoms and unknown long term side effects) and a high value on potential benefits (improvement in quality of life, a small reduction in exacerbations) might consider bronchial thermoplasty."

For patients who opt to choose this intervention via shared decision-making, the panel recommends that clinicians offer the procedure in the setting of a clinical trial or registry study to facilitate the collection of long-term outcomes.

U.S Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

bronchial thermoplasty, Alair, asthma, Alair Bronchial Thermoplasty System, radiofrequency energy

APPROVED BY GOVERNING BODIES:

On April 27, 2010, Alair Bronchial Thermoplasty System (Asthmatx, Inc., Sunnyvale, Ca. now part of Boston Scientific Corporation) 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 long-acting beta-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 two weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

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POLICY HISTORY:

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Medical Policy Group June 2011

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Medical Policy Group, August 2011

Medical Policy Group, September 2011

Medical Policy Group, November 2011

Medical Policy Group, November 2012

Medical Policy Group, July 2013

Medical Policy Group, October 2013

Medical Policy Group, July 2014

Medical Policy Group, July 2015

Medical Policy Group, June 2016

Medical Policy Group, July 2017

Medical Policy Group, July 2018 (7): 2018 Updates to Key Points and References. No change in Policy Statement.

Medical Policy Group, August 2019

Medical Policy Group, June 2020

Medical Policy Group, June 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.