



<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Bronchial Thermoplasty
Policy Number:	MP-019-MC-ALL
Responsible Departments:	Medical Management, Medical Policy
Provider Notice Date:	07/01/2017
Original Effective Date:	08/01/2017
Annual Approval Date:	06/01/2018
Revision Date:	N/A
Products:	Ohio Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 9

#### **DISCLAIMER**

**Gateway Health<sup>SM</sup> (Gateway) clinical medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.**

#### **POLICY STATEMENT**

Gateway Health<sup>SM</sup> does not provide coverage and reimbursement under the medical surgical benefits of the Company Medicare products for the bronchial thermoplasty procedure.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

#### **DEFINITIONS**

**Bronchial Thermoplasty (BT)** – A bronchoscopic procedure in which controlled thermal energy is applied to the airway wall to decrease smooth muscle.

**Airway Smooth Muscle (ASM)** – An important tissue involved in the regulation of bronchomotor tone, exists in the trachea and in the bronchial tree up to the terminal bronchioles. The ASM undergoes marked phenotypic modulation in lung development and in diseases such as asthma, chronic bronchitis, and emphysema.

**Inhaled Corticosteroid (ICS)** – Reduces inflammation in the airways that carry air to the lungs, reduces the mucus made by the lungs (bronchial tubes), and absorbs very small amounts into the body. ICS is used in a metered-dose or dry-powder inhaler. There are less serious side effects with inhaled corticosteroids (e.g., weakening of the bones). ICS is the preferred treatment of long-term control of mild persistent, moderate persistent, or severe persistent asthma symptoms.

**Long-Acting Beta<sub>2</sub> Agonists (LABA)** – Used in combination with a corticosteroid to treat asthma. They are used in a metered-dose or dry-powder inhaler to relax the smooth muscles lining the airways that carry air to the lungs, allowing the bronchial tubes to stay open longer and make breathing easier.

**Sham intervention** – A falsified surgical intervention that omits the step thought to be therapeutically necessary. In clinical trials of surgical intervention, sham surgery is an important scientific control because it isolates specific effects of the treatment as opposed to the incidental effects caused by anesthesia, incisional trauma, pre- and postoperative care, and the patient's perception of having had a regular operation.

## **PROCEDURES**

1. Medical Necessity Guidelines

The Bronchial Thermoplasty procedure is considered experimental and investigational for the treatment of asthma and any other indications because the efficacy and safety have not had efficient establishment.

2. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health<sup>SM</sup> at any time pursuant to the terms of your provider agreement.

## **GOVERNING BODIES APPROVAL**

In April 2010, the Alair<sup>®</sup> Bronchial Thermoplasty System (Asthmatx, Inc. is now part of the Boston Scientific Corporation) was approved by the FDA through the premarket approval process for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with inhaled corticosteroids and LABAs.

### Coverage Determination

Gateway Health<sup>SM</sup> follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

For Ohio, please use the following link for a listing of local coverage determinations by CGS Administrators, LLC:

[https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=238&name=CGS%20Administrators,%20LLC%20\(15202,%20MAC%20-%20Part%20B\)&DocType=Future&ContrVer=2&CntrctrSelected=238\\*2&s=42&bc=AggAAAAIAAA AAAA%3d%3d&#ResultsAnchor](https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=238&name=CGS%20Administrators,%20LLC%20(15202,%20MAC%20-%20Part%20B)&DocType=Future&ContrVer=2&CntrctrSelected=238*2&s=42&bc=AggAAAAIAAA AAAA%3d%3d&#ResultsAnchor)

## **CODING REQUIREMENTS**

### *Noncovered Procedure Codes*

<b>CPT Codes</b>	<b>Description</b>
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

## **SUMMARY OF LITERATURE**

Asthma is one of the most common chronic illnesses that affects the U.S. population (Cangelosi et al., 2014). According to the National Institute of Health and Clinical Excellence (2016), there is no cure for asthma, and five to ten percent of asthma cases are severe and difficult to control. Additionally, there are 17.7 million adults suffering from asthma within the United States, 440,000 hospitalizations per year from asthma exacerbations, and 4,000 asthmatic deaths per year (CDC, 2016). Current asthma management aims at controlling symptoms with minimal side effects, consisting of pharmacological therapies, environmental control, and patient education (Cangelosi et al., 2014). Pharmacological treatment plans administer different combinations of  $\beta_2$  agonists and long-term corticosteroid medications to patients with severe asthma (Wahidi, 2012). Unfortunately, the current treatment plans are not working in some severe persistent asthmatic patients, which is causing morbidity despite the medical community's multidimensional consideration and approach.

The most important factor in minimizing an asthmatic attack is limiting the degree of ASM shortening. The efforts to decrease morbidity and improve quality of life have led to the development of new therapies and asthma treatment approaches. The bronchial thermoplasty is a recently developed therapy designed to weaken and partially destroy the smooth muscle that constricts the airway during an asthma attack (Hayes, 2012). There is a catheter that uses expandable electrodes and a fiber optic camera to pinpoint affected bronchial walls; administering an electrical current to generate the heat from the electrodes will destroy the ASM (Hayes, 2012). A bronchial thermoplasty requires three separate bronchoscopies that are three weeks apart, with moderate sedation and performed in an outpatient setting (Wenzel, 2016). Bronchial thermoplasty is not intended to be performed on individuals with asthma who have a known sensitivity to atropine, benzodiazepines, or lidocaine, or for those with a pacemaker, implantable cardioverter-defibrillator, or other implantable electronic devices. Patients receiving BT therapy will still have a pharmacological treatment plan in addition to the procedures.

### Rationale

In the infancy of the bronchial thermoplasty procedure, there was testing on the mechanism of action and effects in canine models (i.e., animal testing) (Wahidi, 2012). The bronchial thermoplasty was applied to the airways of 11 healthy dogs, and the investigators performed necropsy and histological examinations of the untreated and treated airways at various points in a three-year span (Wahidi, 2012). The canine studies showed success in reducing the increased mass of airway smooth muscle associated with asthma (Wenzel, 2016).

Several clinical trials have been applied to human patients to test the efficacy and safety of the bronchial thermoplasty procedure. There is evidence from three randomized controlled trials (RCTs) and meta-analyses of the RCTs reviewed by several associations and medical professionals. The trials conducted a comparative analysis between BT interventions and sham interventions. The desired outcomes consisted of symptoms, quality of life, hospitalizations, treatment-related morbidity, and exacerbations (Sola, 2014). All trials delivered the thermoplasty adjuvant to conventional pharmacological treatment (Solo, 2014). The first RCTs for the BT procedure (RISA & AIR) were nonrandomized and showed a decrease in rates of mild exacerbations, decreased ER visits and hospitalizations, and improvements to the lung function (Sola, 2014). Although there were significant improvements for severe asthma patients in the two smaller trials, the evidence showed significant post-procedure complications and high serious post-procedure hospitalization rates compared to the control group (Wahidi, 2012). Additionally, there was a contradiction for the BT procedure due to the strong indications for severe asthma, but the initial RCTs excluded patients with more than three exacerbations per year and forced expiratory volume in one second (FEV1) below 50% (Wahidi, 2012). The AIR2 trial (Asthma Intervention Research Trial) was the third and largest RCT and the only trial that was double-blinded and sham-controlled, with testing sites in the U.S. According to the American Journal of Respiratory and Critical Care Medicine (2012), post-treatment for the AIR2 trial documented that 92% of the patients in the intervention group had the same rate of respiratory events in year two as in year one (asthma exacerbations, respiratory adverse events, ER visits, and hospitalizations).

All of the RCTs had a high response rate in the sham groups, which is indicative of a large placebo effect, negatively influencing the strength of the trials (Sola, 2014). According to Dr. Sally Wenzel (2016), “Due to the risk of the procedure and modest degree of improvement, additional data is needed regarding long-term effects and morphologic changes in the airways in order to determine the ideal role for BT in asthma” (Wenzel, 2016).

There are two professional societies among providers and insurers (listed in Table 1) that have encouraged the bronchial thermoplasty to be considered medically necessary. The American College of Chest Physicians (ACCP) (2014) believes the procedure should not be considered experimental due to the reduction in exacerbations, emergency department visits, and days lost from school and work. All of the positive outcomes mentioned by ACCP’s review of the RCTs are reductions in symptoms that were achieved within five years. Although the reduction in symptoms gave modest enhancement to the quality of life, ACCP’s determination places no value on increased mild and moderate respiratory adverse effects. All three RCTs showed a significant increase in hospitalizations among participants during the BT treatment period and were all due to respiratory adverse events (Sola, 2014). During post-treatment, the rate of hospitalizations did not decrease between the BT groups and control groups; BT groups required more hospitalizations for respiratory symptoms than the control groups, over two to three years of follow-up (Sola, 2014). In addition to adverse events, there is limited long-term safety data collected after five years (Wahidi, 2012). Adverse events and limited long-term analyses are not solely responsible for determining the “experimental” status of BT therapy:

- There is no medication step-down after treatment
- Control group participants received a large placebo effect
- A proportion of BT participants did not respond to treatment
- There is uncertain *quality of life* improvements (Sola, 2014)

All of the gathered evidence from the RCTs and meta-analyses have led to the conclusion that bronchial thermoplasty has no developed efficacy in short-term outcome, and there is little data available on the long-term effects of the control population and BT population (due to the large placebo effect) (Wahidi, 2012). The Blue Cross Technology Evaluation Center (TEC) published an assessment (2015) on bronchial thermoplasty for the treatment of inadequately controlled severe asthma. The assessment concluded, “The evidence is insufficient to determine whether potential improvements in some outcomes, but not others defining the net health outcome, outweigh the potential harms,” and the technology did not meet TEC criteria. Additionally, many medical associations and medical professionals associated with asthma treatment have recognized literature and studies indicating the procedure be performed only in the context of a clinical trial or registry until more data can provide substantial evidence regarding the effects of BT (Wenzel, 2016).

*Table 1*

*Please see the following table for rationale information from accredited associations and societies:*

<b>Clinical Association Positions on Bronchial Thermoplasty</b>			
<b>Association</b>	<b>Published Year</b>	<b>Content &amp; Recommendations</b>	<b>Medically Necessary</b>
European Respiratory Society/American Thoracic Society (joint task force)	2014	The guideline was based on a systematic review of the literature. It includes the statement: “We recommend that bronchial thermoplasty is performed in adults with severe asthma only in the context of an Institutional Review Board approved independent systematic registry of a clinical study.” The authors remarked: “This is a strong recommendation, because of the very low confidence in the available estimates of effects of bronchial thermoplasty in patients with severe asthma.”	<b>NO</b>
American Thoracic Society	2013	<ul style="list-style-type: none"> <li>• Recommendation is that bronchial thermoplasty is performed in adults with severe asthma only in the context of an Institutional Review Board-approved independent systematic registry or a clinical study.</li> <li>• Recommendation places a higher value on avoiding adverse effects, on an increased use of resources, lack of understanding of which patients may benefit, and a lower value on the uncertain improvement in symptoms and quality of life.</li> <li>• Potential benefits and harms may be large and the long-term consequences of this new approach to asthma therapy utilizing an invasive physical intervention are unknown.</li> <li>• This is a strong recommendation, because of the very low confidence in the currently available estimates of effects of bronchial thermoplasty in patients with severe asthma.</li> </ul>	<b>NO</b>

<p>American College of Allergy, Asthma and Immunology (ACCA)</p>	<p>2015</p>	<ul style="list-style-type: none"> <li>• The scientific literature supports bronchial thermoplasty as a therapeutic consideration for some carefully chosen patients with severe asthma.</li> <li>• Carefully selected patients with severe, persistent asthma who have persistent burden of disease, asthma exacerbations, emergency department visits or hospitalizations despite maximal medical treatment may benefit from this procedure.</li> <li>• The ACAAI recommends that insured provide coverage for the bronchial thermoplasty for those adult patients that meet the stringent requirements.</li> </ul>	<p>YES</p>
<p>American College of Chest Physicians (ACCP)</p>	<p>2014</p>	<ul style="list-style-type: none"> <li>• ACCP 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.</li> <li>• 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.</li> <li>• Denying bronchial thermoplasty to those carefully selected patients with severe persistent asthma can leave them with continued asthma exacerbations, frequent hospitalizations, and missed school or work days.</li> <li>• The procedure will provide physicians and patients with a safe and effective treatment option and allow the medical and payer community to develop utilization and outcomes data in their own populations.</li> </ul>	<p>YES</p>
<p>Global Initiative for Asthma (GINA)</p>	<p>2014</p>	<ul style="list-style-type: none"> <li>• The treatment is associated with a large placebo effect.</li> <li>• In patients taking high-dose ICS/LABA, bronchial thermoplasty was associated with an increase in asthma exacerbations during the 3 month treatment period, and a subsequent decrease in exacerbations, but no beneficial effect on lung function or asthma symptoms compared with sham-controlled patients.</li> <li>• Extended follow up of some treated patients reported a sustained reduction in exacerbations compared with pre-treatment. However, longer-term follow up of larger cohorts comparing effectiveness and safety, including for lung function, in both active and sham-treated patients is needed.</li> </ul>	<p>NO</p>

National Institute of Health and Clinical Excellence (NICE)	2016	<ul style="list-style-type: none"> <li>• Three trials showed patient benefits associated with using the BT (including improved quality of life and morning expiratory flow) but there is uncertain clinical significance regarding benefits.</li> <li>• The trials also showed mixed evidence in relation to adverse outcomes (including asthma exacerbations, hospitalizations and ER visits).</li> </ul>	<b>NO</b>
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## **REIMBURSEMENT**

Participating facilities will be reimbursed per their Gateway Health<sup>SM</sup> contract.

## **POLICY SOURCE(S)**

American Academy of Allergy Asthma & Immunology. Bronchial Thermoplasty Provides Long Term Asthma Control, September 3, 2013. Accessed on January 25, 2017 and available at: <http://www.aaaai.org/home>.

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National Institute for Health and Care Excellence. Alair bronchial thermoplasty system for adults with severe difficult to control asthma: Medtech innovation briefing, July 2016. Accessed on January 25, 2017 and available at: <https://www.nice.org.uk/guidance/mib71/resources/alair-bronchial-thermoplasty-system-for-adults-with-severe-difficult-to-control-asthma-63499342420933>.

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Wenzel, S. Treatment of severe asthma in adolescents and adults. UpToDate: Wolters Kluwer, December 2016. Accessed on January 24, 2017 and available at: [https://www.uptodate.com/contents/treatment-of-severe-asthma-in-adolescents-and-adults?source=search\\_result&search=Treatment%20of%20severe%20asthma%20in%20adolescents%20and%20adults.&selectedTitle=1~150](https://www.uptodate.com/contents/treatment-of-severe-asthma-in-adolescents-and-adults?source=search_result&search=Treatment%20of%20severe%20asthma%20in%20adolescents%20and%20adults.&selectedTitle=1~150).



### Policy History

Date	Activity
06/02/2017	Initial policy developed
06/21/2017	QI/UM Committee approval
08/01/2017	Provider effective date