



CLINICAL MEDICAL POLICY	
<b>Policy Name:</b>	Bronchial Thermoplasty
<b>Policy Number:</b>	MP-019-MC-PA
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice/Issue Date:</b>	08/01/2024; 08/01/2023; 09/01/2022; 06/18/2021; 06/29/2020; 07/15/2019; 07/15/2018
<b>Effective Date:</b>	09/01/2024; 09/01/2023; 10/01/2022; 07/19/2021; 07/27/2020; 07/15/2019
<b>Next Annual Review:</b>	07/2025
<b>Revision Date:</b>	07/17/2024; 07/19/2023; 07/20/2022; 05/19/2021; 05/20/2020; 05/15/2019
<b>Products:</b>	Pennsylvania Medicare Assured
<b>Application:</b>	All participating and nonparticipating practitioners and facilities unless contractually precluded
<b>Page Number(s):</b>	1 of 10

#### Policy History

Date	Activity
09/01/2024	Provider Effective date
07/17/2024	QI/UM Committee review
07/17/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2023	Provider Effective date
07/19/2023	QI/UM Committee review
07/19/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
10/01/2022	Provider Effective date
07/20/2022	QI/UM Committee review
07/20/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/19/2021	Provider effective date
05/19/2021	QI/UM Committee review
05/19/2021	Annual Review: No changes to clinical criteria. Updated Summary of Literature and Reference sections.
07/27/2020	Provider effective date

05/20/2020	QI/UM Committee review
05/20/2020	Annual Review: No clinical criteria changes; removed the hyperlinks; updated Summary of Literature and Reference sections
07/15/2019	Provider effective date
05/15/2019	QI/UM Committee review
05/15/2019	Annual Review: Added anti-IGE & anti-Interleukin II failure to medical necessity criteria; expanded noncoverage conditions to include GERD, chronic aspiration, severe allergies and vocal cord dysfunction; update all GINA references; removed hyperlinks from all references
06/02/2017	Initial policy developed

### **Disclaimer**

Highmark Wholecare<sup>SM</sup> 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**

Highmark Wholecare<sup>SM</sup> may provide coverage under the medical surgical benefits of the Company's Medicare products for medically necessary bronchial thermoplasty.

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 Beta2 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.

**Severe persistent asthma** – A patient has asthma symptoms every day. The patient may also needs to use a rescue inhaler daily to treat shortness of breath. The normal activities are affected by wheezing, shortness of breath, or chest tightness.

**Academic medical center** – Academia is a health care organization that is often linked to a medical school and hospital complex missions: teaching of medical students and physicians in training; research; 3<sup>o</sup> patient care in close affiliation or as part of a degree-granting university. An academic center:

- Provides patients and the community with health care for everyday needs and the most specialized services for complex diseases, illnesses and injuries.
- Offers unique care not available anywhere else in the region
- Teaches generations of healthcare professionals with an eye on training the right mix of providers for tomorrow’s needs.
- Develops technology and carries out research that improves lives.

## **Procedures**

Recommendations from the National Institute of Health’s National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group “Focused Updates to the Asthma Management Guidelines” conditionally recommend against the use of bronchial thermoplasty, with an assessment of small benefits, moderate risk, and uncertain long-term outcomes.

1. Bronchial thermoplasty will be considered medically necessary when ALL of the following criteria has been met:
  - A. The patient must be age 18 years or older; AND
  - B. The patient has been managed by an asthma specialist for at least 6 months; AND
  - C. The patient must have a confirmed diagnosis of severe, persistent asthma by having ANY ONE of the following criteria in the absence of controller medications:
    - a) Daily asthma symptoms; OR
    - b) Night time awakenings, every night; OR
    - c) Use of rescue medicine multiple times per day; OR
    - d) Normal activities are extremely limited; OR
    - e) Impaired lung function (less than or equal to 60% predicted); OR
    - f) Frequent exacerbations; AND
  - D. Co-morbid conditions (e.g., allergies, GERD) contributing to asthma exacerbations have been ruled out or fully controlled; AND
  - E. The patient is not a candidate for, or has failed, treatment with omalizumab; AND
  - F. The patient has failed, is intolerant to, or is not a candidate for anti-IgE therapy or anti-Interleukin (II)-5 therapy; AND

- G. The patient is not a current or recent smoker (i.e., within 12 months); AND
  - H. The patient has poor symptom control with EITHER of the following:
    - a) Inhaled corticosteroids (ICS) and long acting beta agonists (LABA); OR
    - b) Requiring chronic (>3 months) oral corticosteroids; AND
  - I. The patient has had at least three (3) emergency department visits or hospitalizations for asthma in the preceding twelve (12) months; AND
  - J. The requesting physician must be a pulmonologist who has completed a bronchial thermoplasty training curriculum; AND  
The surgical procedure must be done at an academic center (*e.g. Allegheny Health Network (AHN), University of Pittsburgh Medical Center (UPMC), or Thomas Jefferson University*).
2. Bronchial thermoplasty is considered not medically necessary for any conditions other those listed above because the scientific evidence has not been established, including, but not limited to:
- The presence of a pacemaker, internal defibrillator, or other implantable electronic device
  - A known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, or benzodiazepines
  - Patients who were previously treated prior to full course of bronchial thermoplasty
  - Patients with an active respiratory infection
  - Patients who have an asthma exacerbation or is changing dosing of systemic corticosteroids for asthma (up or down) in the past 14 days
  - There is a known coagulopathy
  - Gastroesophageal reflux disease, uncontrolled or untreated
  - Chronic aspiration
  - Severe allergies
  - Vocal cord dysfunction
3. Post-payment Audit Statement  
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare<sup>SM</sup> at any time pursuant to the terms of your provider agreement.
4. Place of Service  
The proper place of services for the bronchial thermoplasty procedure is in the outpatient setting.

### **Governing Bodies Approval**

In April 2010, the Alair® 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.

The use of a bronchial thermoplasty device outside of the listed FDA guidelines will require approval from a Medical Director on a case-by-case basis.

## CMS

Highmark Wholecare<sup>SM</sup> follows the coverage determinations made by Centers for Medicare and Medicaid Services (CMS) as outlined in either the national coverage determinations (NCD) or the state-specific local coverage determination (LCD). Medicare does not have a NCD for bronchial thermoplasty. At the time of this policy development, a LCD was not available.

## **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 19.2 million adults currently living with asthma within the United States, along with an estimated 9.8 million emergency department visits per year with asthma listed as the primary diagnosis, and 3.524 deaths annually from the disease (CDC, 2021). 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.

Bronchial thermoplasty will help patients with severe persistent asthma that do not respond to high-dose inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA); who have reached the end-stages of typical asthma treatments (Boston Scientific, 2017). 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.

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). The AIR2 trial demonstrated an important safety data on the 5-year follow-up of 85% of asthma patients (Chung, 2014). 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 three professional societies among providers and insurers (listed in *Table 2*) that have encouraged the bronchial thermoplasty to be considered medically necessary. The American College of Chest Physicians (2014) believes the procedure offers treatment for patients with severe asthma who continue to be symptomatic despite maximal medical treatment. All of the positive outcomes mentioned by CHEST'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, CHEST's determination places no value on increased mild and moderate respiratory adverse effects. Some of the 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). Several other issues were presented with bronchial thermoplasty, including:

- 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)

According to Chupp et al., (2017), there is efficacy of bronchial thermoplasty within the confines of a randomized controlled clinical trial but more “real world” clinical outcome data is needed in order to recommend the bronchial thermoplasty out of a controlled environment.

The Global Initiative for Asthma (GINA) is an international organization in which the members are asthma experts. This group has been publishing the Global Strategy for Asthma Management and Prevention since 2002 and the most recent update was issued in 2020. The group supports the use of stepped care for asthma which consists of 5 distinct steps.

- Step 1 is the use of an as-needed low dose combination inhaled corticosteroids (ICS)-formoterol (for adults and adolescents).
- Step 2 is a daily low-dose ICS plus as-needed Short-acting  $\beta$ -agonist (SABA) or as-needed low-dose ICS-formoterol (for adults and adolescents)
- Step 3 is the use of a low-dose ICS-LABA (Long-acting beta-agonists) maintenance plus as-needed SABA, or low dose ICS-formoterol maintenance and reliever therapy (adults and adolescents); medium dose ICS plus as-needed SABA or low-dose combination ICS-LABA plus as-needed SABA (children 6-11 years)
- Step 4 is the use of a low dose ICS-formoterol as maintenance and reliever therapy (adults and adolescents), or medium dose ICS-LABA maintenance plus as-needed SABA (adults, adolescents and children)
- Step 5 recommends the patient be referred for phenotypic assessment and consideration of add-on treatment (adults, adolescents, and children).

GINA advises that bronchial thermoplasty is a potential treatment option at Step 5 for adult patients whose asthma remains uncontrolled despite optimized therapeutic regimens and referral to an asthma specialty center (Global Initiative for Asthma, 2020).

In a 2020 update, the GINA strategy stated that if there is no evidence of Type 2 inflammation, the healthcare provider should consider non-biologic treatments. One of the treatments identified is a consideration for bronchial thermoplasty plus registry enrollment. It is noted that the scientific evidence for efficacy and long term safety remains limited. The guidelines also indicate that in patients with no good response to type 2-targeted therapy, bronchial thermoplasty plus registry enrollment may be considered.

#### 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). 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 eight clinical trials examining patients with severe, not well-controlled asthma; four of which include 5-year follow-up data. Please see *Table 1* for the summary of the clinical trials. The desired outcomes consisted of symptoms, quality of life, hospitalizations, treatment-related morbidity, and exacerbations. All trials delivered the thermoplasty adjuvant to conventional pharmacological treatment. The RISA & AIR RCTs for the BT procedure were nonrandomized and showed a decrease in rates of mild exacerbations, decreased ER visits and hospitalizations, and improvements to the lung function (Sola, 2014).

The studies summarized in *Table 1* below all demonstrate a stable long-term safety profile up to 5 years (Boston Scientific, 2017). 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. 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.

A meta-analysis conducted by Zhou, et al., evaluated the long-term efficacy and safety of bronchial thermoplasty (BT) in the treatment of patients with moderate-to-severe persistent asthma. A systematic literature review of peer-reviewed studies was performed, focusing on BT intervention in asthma control published between January 2000 and June 2014. Three randomized controlled studies and extension studies met the inclusion criteria (n = 6). The outcomes were assessed after BT included spirometric data, adverse respiratory events, emergency room (ER) visits and hospitalization for respiratory illness. One-year and 5-year follow-up data were defined as V1 and V5, respectively. There were 249 BT-treated subjects in total who had a 1-year follow-up (V1), whereas 216 of them finished a 5-year follow-up (V5). No evidence of significant decline was found in pre-bronchodilator FEV1 (% predicted) (WMD = 0.75; 95% CI: 3.36 to 1.85; p = 0.57), or in post-bronchodilator FEV1 (% predicted) (WMD = 0.62; 95% CI: 3.32 to 2.08; p = 0.65) between V1 and V5. This data evidence demonstrated the long-term benefits of BT with regard to both asthma control and safety for moderate-to-severe asthmatic patients (Zhou, et al., 2016).

The AIR2 (Asthma Intervention Research) trial, the largest study of bronchial thermoplasty to date, was a sham-controlled clinical trial of nearly 290 adults with severe asthma (1). Participants in both the bronchial and sham thermoplasty groups reported improvements in asthma quality of life over 12 months (the primary outcome), which was assessed by the Asthma Quality of Life Questionnaire (AQLQ). Importantly, both groups reported more than twice the minimum important difference for the AQLQ. However, the difference between groups in the AQLQ was modest and less than the minimum important difference over 12 months. Although some secondary outcomes favored bronchial thermoplasty (asthma exacerbations treated and days lost from school or work) over 12 months, there were no differences between groups in respiratory symptoms, rescue medication use, or lung function. Also, 8% of participants undergoing bronchial thermoplasty (vs. 2% in the sham group) required hospitalizations because of procedure-related complications (Krishnan & Husain, 2021).

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- Bronchial Thermoplasty for Treatment of Asthma in Adults
  - **C Rating** - For bronchial thermoplasty (BT) for treatment of severe persistent asthma in adult patients (18 years or older) whose asthma has not been well controlled by long-acting bronchodilators and glucocorticoids and who accept the short-term risk of increased adverse events.
  - **D2 Rating** - For BT for treatment of mild to moderate asthma in adults.

A low-quality body of evidence suggests that BT may reduce asthma exacerbations, healthcare utilization, and medication usage and may improve symptom control and asthma-related quality of life (QOL) in patients with severe asthma. Improvements in symptom control and quality-of-life measures following BT relative to baseline values were generally clinically significant. However, several studies showed inconsistent benefit across multiple outcomes. Pulmonary function measures are not improved with BT. Comparative data were available through 1 year after thermoplasty, while open-label follow-up was available for up to 10 years post BT and generally showed a sustained benefit compared with baseline. Adverse events were common during the BT treatment period. Further studies should seek to determine which patients with severe asthma are most likely to benefit from treatment and evaluate the relative effectiveness of BT compared with other add-on treatments for severe persistent asthma, including monoclonal antibody therapies.

### **Coding Requirements**

#### Procedure Codes

CPT Code	Description
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

The above two CPT codes are mapped to Ambulatory Payment Classification (APC), Level 5 Airway Endoscopy.

#### Diagnosis Codes

ICD-10 Code	Description
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus

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