

CLINICAL MEDICAL POLICY	
Policy Name:	Bronchial Thermoplasty
Policy Number:	MP-050-MD-DE
Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

DISCLAIMER

Highmark Health Options 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 Health Options may provide coverage under the medical surgical benefits of the Company's Medicaid 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

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 – The patient has asthma symptoms every day. The patient may also need 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 – A Academia health care organization that is often linked to a medical school and hospital complex missions: teaching of medical students and physicians in training; research; 3rd patient care in close affiliation, or as part of a degree-granting university. An academic medical 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 health care 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

1. Medical Necessity Guidelines
 - A. The patient must be age 18 years or older; AND
 - B. The patient has to be 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:

- 1) Daily symptoms; OR
- 2) Night time awakenings, every night; OR
- 3) Use of rescue medicine multiple times per day; OR
- 4) Normal activities are extremely limited; OR
- 5) Impaired lung function (less than or equal to 60% predicted); OR
- 6) 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:
 - 1) Inhaled corticosteroids (ICS) and long acting beta agonists (LABA); OR
 - 2) Requiring chronic (> 3 months) oral corticosteroids;
- AND
- I. The patient has had at least three emergency department visits or hospitalizations for asthma in the preceding 12 months; AND
 - J. The requesting physician must be a pulmonologist who has completed a bronchial thermoplasty training curriculum; AND
 - K. The surgical procedure must be done at an academic center (e.g., Allegheny Health Network (AHN), University of Pittsburgh Medical Center (UPMC), and Thomas Jefferson University).

2. When bronchial thermoplasty is not covered

Bronchial thermoplasty is not covered for conditions other than those listed above because the scientific evidence has not been established, including but not limited to:

- A. The presence of a pacemaker, internal defibrillator, or other implantable electronic device; OR
- B. A known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines; OR
- C. The patient was previously treated prior to full course of bronchial thermoplasty; OR
- D. The patient has an active respiratory infection; OR
- E. The patient has had an asthma exacerbation or is changing dosing of systemic corticosteroids for asthma (up or down) in the past 14 days; OR
- F. There is a known coagulopathy; OR
- G. Gastroesophageal reflux disease; OR
- H. Chronic aspiration
- I. Severe allergies
- J. 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 Health Options at any time pursuant to the terms of your provider agreement.

4. Place of Service

The place of services for the bronchial thermoplasty procedure is 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.

CODING REQUIREMENTS

Procedure Codes

CPT Codes	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

Diagnosis Codes

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

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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 b_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 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 (Sola, 2014). All trials delivered the thermoplasty adjuvant to conventional pharmacological treatment (Solo, 2014). 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* 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 (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). 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 reductions 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). 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)

According to Geoffrey Chupp (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. Hayes, Inc. (2016) published a position and rating which indicates a C rating. The C rating was determined due to a small collection of low-quality evidence of the long-term safety and efficacy of the bronchial thermoplasty procedure (Hayes, 2016). Similar to other accredited institutions, Hayes reported a significant increase in complications, loss of effectiveness in the long-term follow-up, and a host of clinical trial inconsistencies (e.g., numerous poor quality trials and insufficient clinical trials) (Hayes, 2016).

2018 Update

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 2018. The group supports the use of stepped care for asthma which consists of 4 steps. Step 1 is the use of reliever inhaler on as needed basis. Step 2 involves low-dose controller medication AND an as needed reliever medication. In Step 3 use of one or two controllers plus an as needed reliever medication. Step 5 consist of higher level care and/or the inclusion of add-on treatments. In Step 5, GINA has included the option for bronchial thermoplasty for a select group of adult patients with asthma. The group advises that bronchial thermoplasty should only be performed in adults with severe asthma whose condition remains uncontrolled despite application of recommended therapeutic regimens and referral to an asthma center (Evidence B); and that caution should be used in the selecting patients for the procedure. The number of studies is small and people with chronic sinus disease, frequent chest infections or FEV1<60% predicted were excluded.

Table 1

Clinical Trials on Bronchial Thermoplasty				
Study Title	Study Description	Related Publications	No. of Patients	Key Findings
PAS2 (Post Approval Study)	Long-term durability and real-world effectiveness of BT	Chupp et al., ERJ 2017	190 BT patients with 3-year data; 284 total patients enrolled	<ul style="list-style-type: none"> Effectiveness maintained long-term and real-world experience of BT patients is similar to the experience of patients studied within the AIR2 clinical trial. Real-world effectiveness demonstrated for a patient cohort that could be interpreted as more poorly controlled than the cohort included in the AIR2 Trial.
AIR2 Trial Extension Study (FDA "Pivotal Trail")	Long-term durability of effectiveness (in BT treated patients in the AIR2 Trial)	Wechsler et al., JACI 2013	181 BT	<ul style="list-style-type: none"> Effectiveness maintained long-term, demonstrated by sustained reduction in the proportion of patients with severe exacerbations out to 5 years Stable long term safety profile (5 year follow-up)
AIR2 Trial	Randomized, double-blind, sham-controlled trial to evaluate effectiveness and safety in patients with severe asthma	Castro et al., AnnAAI 2011	196 BT, 101 Sham	<ul style="list-style-type: none"> 32% reduction in severe exacerbations 84% reduction in ER visits for respiratory symptoms 73% reduction in hospitalizations for respiratory symptoms 66% reduction in days lost from work/school/ other daily activities due to asthma symptoms Stable long term safety profile (1 year follow-up)
AIR Trial	Randomized, controlled (to standard-of-care) trial to evaluate efficacy and safety in patients with moderate to severe asthma	Castro et al., AJRCCM 2010	56 BT, 56 Control	<ul style="list-style-type: none"> 50% reduction in exacerbations Overall improvements in measures of asthma control Stable long-term safety profile (1 year follow-up)
AIR Trial Extension	Long-term (5 year) safety of Bronchial Thermoplasty (in BT-treated patients in the AIR Trial)	Cox et al., NEJM 2007	45 BT	<ul style="list-style-type: none"> Stable long-term safety profile out to 5 years
RISA Trial	Randomized, controlled (to standard-of-care) trial to evaluate safety in patients with severe, refractory asthma	Thomson et al., BMC Pulmonary Medicine 2011	15 BT, 17 Control	<ul style="list-style-type: none"> Stable, long-term safety profile (1 year follow-up) Improvements in measures of asthma control Strong suggestion of reduction in OCS use
RISA Trial Extension	Long-term safety (5 year) of Bronchial Thermoplasty (in Bronchial Thermoplasty (in BT-treated patients in the RISA Trial)	Pavord et al., AJRCCM 2007	14 BT	<ul style="list-style-type: none"> Stable long-term safety profile out to 5 years
Feasibility Study	Safety study in patients with mild to severe asthma; Patient satisfaction survey	Cox et al., AJRCCM 2006 Wilson et al., JOR 2006 Cox et al., AJRCCM 2010, A6839	16 BT	<ul style="list-style-type: none"> Stable long-term safety profile (5 year follow-up) No clinically significant observations in high resolution CT scans out to 5 years All patients reported a willingness to undergo the procedure again and to recommend it to others Patients reported an increased ability to carry out activity, increased tolerance to allergens, and increased tolerance for physical exertion

<https://www.bostonscientific.com/en-US/products/bronchial-thermoplasty.html>

Table 2

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
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.”	YES
American Thoracic Society	2013	<ul style="list-style-type: none"> • 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. • 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. • 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. • 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. 	NO
American College of Allergy, Asthma and Immunology (ACCA)	2015	<ul style="list-style-type: none"> • The scientific literature supports bronchial thermoplasty as a therapeutic consideration for some carefully chosen patients with severe asthma. • 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. • The ACAAI recommends that insured provide coverage for the bronchial thermoplasty for those adult patients that meet the stringent requirements. 	YES

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
American College of Chest Physicians (ACCP)	2014	<ul style="list-style-type: none"> • 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. • 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. • 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. • 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. 	YES
Global Initiative for Asthma (GINA)	2014 2018	<ul style="list-style-type: none"> • The treatment is associated with a large placebo effect. • 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. • 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. <p>The group supports the use of stepped care for asthma which consists of 4 steps. Step 1 is the use of reliever inhaler on as needed basis. Step 2 involves low-dose controller medication AND an as needed reliever medication. In Step 3 use of one or two controllers plus an as needed reliever medication. Step 5 consist of higher level care and/or the inclusion of add-on treatments. In Step 5, GINA has included the option for</p>	NO

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
		bronchial thermoplasty for a select group of adult patients with asthma. The group advises that bronchial thermoplasty should only be performed in adults with severe asthma whose condition remains uncontrolled despite application of recommended therapeutic regimens and referral to an asthma center (Evidence B); and that caution should be used in the selecting patients for the procedure. The number of studies is small and people with chronic sinus disease, frequent chest infections or FEV1<60% predicted were excluded.	
National Institute of Health and Clinical Excellence (NICE)	2016	<ul style="list-style-type: none"> • 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. • The trials also showed mixed evidence in relation to adverse outcomes (including asthma exacerbations, hospitalizations and ER visits). 	NO

POLICY SOURCE(S)

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Policy History

Date	Activity
02/09/2017	Initial policy developed
06/27/2017	QI/UM Committee approval
08/09/2017	Added Disclaimer Statement in opening policy box. EHS Revisions: Added Issue Date to opening policy box, updated Operational Guidelines
09/01/2017	Provider effective date
12/01/2017	Policy Revision: Updated Definition section; removed investigational coverage determination & Added medical necessity guidelines for the procedure. Table 1 replaced with new Clinical Trial table; Deleted Hayes Classification System table; Revised Summary of Literature; Added covered ICD-10 diagnosis codes and updated references.
03/31/2018	QI/UM Committee Review Approval
05/15/2018	New Provider effective date
04/19/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
03/12/2019	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; updated Operational guidelines regarding medical necessity denials; update all GINA references; removed hyperlinks from all references
03/12/2019	QI/UM Committee Review Approval
05/06/2019	Provider effective date