



<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Bronchial Thermoplasty
<b>Policy Number:</b>	MP-050-MD-PA
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice/Issue Date:</b>	09/01/2022; 08/20/2021; 07/16/2021; 03/19/2021; 02/17/2020; 03/19/2019; 04/15/2018; 07/19/2017
<b>Effective Date:</b>	10/01/2022; 09/20/2021 ; 08/16/2021; 04/19/2021; 03/16/2020; 03/19/2019; 04/15/2018; 07/19/2017
<b>Next Annual Review:</b>	06/2023
<b>Revision Date:</b>	07/20/2022; 07/21/2021; 06/16/2021; 11/18/2020; 12/18/2019; 12/19/2018; 12/01/2017; 08/09/2017
<b>Products:</b>	Highmark Wholecare <sup>SM</sup> Medicaid
<b>Application:</b>	All participating hospitals and providers
<b>Page Number(s):</b>	1 of 14

### Policy History

Date	Activity
10/01/2022	Provider Effective date
08/16/2022	PARP approval
07/20/2022	QI/UM Committee review
07/20/2022	Annual Review: No changes to clinical criteria. Reformatted 'Procedure' section numbering. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/20/2021	Provider effective date
08/09/2021	PARP approval
07/21/2021	QI/UM Committee review
07/21/2021	Urgent Review: Added 'Program Exception' statement in regards to TAG Option #3 determination
07/08/2021	PARP Approval
06/16/2021	QI/UM Committee review
06/16/2021	Annual Review: Added TAG determination information, with formatting changes to Procedures section. Updated Summary of Literature and References section.
04/19/2021	Provider Effective Date
02/24/2021	PARP Approval
11/18/2020	QI/UM Committee Review
11/18/2020	Annual Review: updated Summary of Literature and References sections, removed disabled hyperlink, updated Table 2.
03/16/2020	Provider Effective Date

01/13/2020	PARP Approval
12/18/2019	QI/UM Committee Review
12/18/2019	Annual Review: No changes
03/19/2019	Provider effective date
01/09/2019	PARP Approval
12/19/2018	QI/UM Committee review
12/19/2018	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
04/19/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
04/15/2018	Provider Effective Date
01/18/2018	PARP Approval
12/20/2017	QI/UM Committee Review
12/01/2017	Policy change of medical necessity status
08/09/2017	EHS Revisions: Added Issue Date to opening policy box, updated Operational Guidelines
07/19/2017	Provider effective date
05/01/2017	Resubmission to PARP
04/25/2017	Revision: Corrected Operational Guidelines from pre-post payment not applicable to preservice, prepayment for professional and facility claims.
03/17/2017	PARP Approval
02/15/2017	QI/UM Committee review
02/09/2017	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 Medicaid products for the use of the bronchial thermoplasty procedure for asthma.

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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

## **Definitions**

**Prior Authorization Review Panel (PARP)** – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

**Bronchial Thermoplasty (BT)** – A bronchoscopic procedure in which controlled thermal energy is applied to the airway wall to decrease smooth muscle. A complete bronchial thermoplasty procedure is performed in three treatment sessions with a recovery period of 3 weeks or longer between treatment sessions.

**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.

**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.

## **Bronchial Thermoplasty is considered not medically necessary unless approved by a Program Exception.**

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

In November 2017, the TAG workgroup assigned bronchial thermoplasty an Option # 3, specifically for CPT codes 31660 and 31661.

Although clinical input obtained from the Department of Health Services TAG does not reflect the consensus support for this procedure among clinicians, those who did support this procedure noted that they supported it for patients who have no other options for severe, persistent asthma (TAG, 2017).

### **Program Exception**

Bronchial thermoplasty requires a program exception, the ordering physician must provide a supporting statement indicating why a requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

### **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. Requests for program exceptions will be reviewed by a Medical Director on a case by case basis, and at a minimum, the request must document ALL of the following:
  - A. The specific benefit of this therapy over other comparable therapies; AND
  - B. Documentation that the following Medical Necessity Guidelines are met:
    - 1) The patient must be age 18 years or older; AND
    - 2) The patient has been managed by an asthma specialist for at least 6 months; AND
    - 3) 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
    - 4) Co-morbid conditions (e.g., allergies, GERD) contributing to asthma exacerbations have been ruled out or fully controlled; AND

- 5) The patient is not a candidate for, or has failed, treatment with omalizumab; AND
  - 6) The patient has failed, is intolerant to, or is not a candidate for anti-IgE therapy or anti-Interleukin (II)-5 therapy; AND
  - 7) The patient is not a current or recent smoker (i.e., within 12 months); AND
  - 8) The patient has poor symptom control with either:
    - a) Inhaled corticosteroids (ICS) and long acting beta agonists (LABA); OR
    - b) Requiring chronic (>3 months) oral corticosteroids; AND
  - 9) The patient has had at least three emergency department visits or hospitalizations for asthma in the preceding 12 months; AND
  - 10) 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), and Thomas Jefferson University*).
2. Bronchial thermoplasty is not covered for any conditions other than those listed above as 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 and benzodiazepines
  - The patient was previously treated prior to full course of bronchial thermoplasty
  - The patient has an active respiratory infection
  - The patient has had 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
  - 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<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.

## **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  $b_2$  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 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 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).



## Informational

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"> <li>Effectiveness maintained long-term and real-world experience of BT patients is similar to the experience of patients studied within the AIR2 clinical trial.</li> <li>Real-world effectiveness demonstrated for a patient cohort that could be interpreted as more poorly controlled than the cohort included in the AIR2 trial.</li> </ul>
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"> <li>Effectiveness maintained long-term, demonstrated by sustained reduction in the proportion of patients with severe exacerbations out to 5 years</li> <li>Stable long term safety profile (5 year follow-up)</li> </ul>
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"> <li>32% reduction in severe exacerbations</li> <li>84% reduction in ER visits for respiratory symptoms</li> <li>73% reduction in hospitalizations for respiratory symptoms</li> <li>66% reduction in days lost from work/school/ other daily activities due to asthma symptoms</li> <li>Stable long term safety profile (1 year follow-up)</li> </ul>
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"> <li>50% reduction in exacerbations</li> <li>Overall improvements in measures of asthma control</li> <li>Stable long-term safety profile (1 year follow-up)</li> </ul>
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"> <li>Stable long-term safety profile out to 5 years</li> </ul>
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"> <li>Stable, long-term safety profile (1 year follow-up)</li> <li>Improvements in measures of asthma control</li> <li>Strong suggestion of reduction in OCS use</li> </ul>
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"> <li>Stable long-term safety profile out to 5 years</li> </ul>
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"> <li>Stable long-term safety profile (5 year follow-up)</li> <li>No clinically significant observations in high resolution CT scans out to 5 years</li> <li>All patients reported a willingness to undergo the procedure again and to recommend it to others</li> <li>Patients reported an increased ability to carry out activity, increased tolerance to allergens, and increased tolerance for physical exertion</li> </ul>

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
European Respiratory Society/American Thoracic Society (joint task force)	2014	<ul style="list-style-type: none"> <li>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."</li> </ul>	YES
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>	NO
American College of Allergy, Asthma and Immunology (ACCAI)	2015	<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 ACCAI recommends that insured provide coverage for the bronchial thermoplasty for those adult patients that meet the stringent requirements.</li> </ul>	YES
American College of Chest Physicians (ACCP)	2014	<ul style="list-style-type: none"> <li>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</li> </ul>	YES

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
		<p>despite maximal medical treatment and, therefore should not be considered experimental.</p> <ul style="list-style-type: none"> <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>	
Global Initiative for Asthma (GINA)	2020	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Caution should be used in selecting patients for this procedure.</li> <li>• Bronchial thermoplasty should be performed in adults with severe asthma only in the context of an independent Institutional Review Board-approved systematic registry or a clinical study, so that further evidence about effectiveness and safety of the procedure can be accumulated.</li> </ul>	<b>YES</b>
National Institute of Health and Care 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>

Clinical Association Positions on Bronchial Thermoplasty			
Association	Published Year	Content & Recommendations	Medically Necessary
National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group	2020	<ul style="list-style-type: none"> <li>In individuals ages 18 and older with persistent asthma, the Expert Panel conditionally recommends against bronchial thermoplasty (Conditional recommendation, low certainty of evidence)</li> <li>Individuals ages 18 years and older with persistent asthma who place a low value on harms (i.e., short-term worsening of symptoms and unknown long-term side effects) and a high value on potential benefits (i.e., improvement in quality of life and a small reduction in number of exacerbations) might consider BT.</li> </ul>	YES

**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

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

**Reimbursement**

Participating facilities will be reimbursed per their Highmark Wholecare<sup>SM</sup> contract.

## **Reference Sources**

American Academy of Allergy Asthma & Immunology. Bronchial Thermoplasty Provides Long Term Asthma Control. September 3, 2013. Accessed on October 15, 2020.

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Centers for Disease Control and Prevention. Asthma FastStats. Accessed on September 16, 2020.

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