CLINICAL MEDICAL POLICY	
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Responsible Department(s):	Medical Management
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
10/01/2024	Provider Effective date
08/13/2024	PARP Approval
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.
10/01/2023	Provider Effective date
08/15/2023	PARP Approval
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
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
02/09/2017	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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℠ 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$_2$ 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; 3º 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

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 individuals 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.

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 a Program Exception will be reviewed by a Medical Director on a case-by-case basis. 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 individual must be age 18 years or older; AND
      2) The individual has been managed by an asthma specialist for at least six (6) months; AND
      3) The individual 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 individual is not a candidate for, or has failed, treatment with omalizumab; AND
      6) The individual has failed, is intolerant to, or is not a candidate for anti-IgE therapy or anti-Interleukin (II)-5 therapy; AND
      7) The individual is not a current or recent smoker (i.e., within 12 months); AND
      8) The individual 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
      9) The individual has had at least three (3) emergency department visits OR hospitalizations for asthma in the preceding twelve (12) months; AND
      10) The requesting physician must be a pulmonologist who has completed a bronchial thermoplasty training curriculum; AND
      11) 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 Hospital*).

2. Bronchial thermoplasty is considered not medically necessary 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, or benzodiazepines
- Individuals who were previously treated prior to full course of bronchial thermoplasty
- Individuals with an active respiratory infection
- Individuals who have had an asthma exacerbation or is changing dosing of systemic corticosteroids for asthma (up or down) in the past 14 days
- There is 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℠ 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.

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 8.7% of the adult population in the U.S. is currently living with asthma, along with an estimated 939,000 emergency department visits per year with asthma listed as the primary diagnosis, and 3,602 deaths annually from the disease (CDC, 2024). 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.

Bronchial thermoplasty is a non-drug procedure for severe asthmatics whose asthma is not properly controlled with inhaled corticosteroids and long-lasting beta-antagonists. Bronchial thermoplasty delivers

thermal energy to the lungs to decrease the amount of smooth muscle in the lungs. By reducing the smooth muscle, the airways are not able to constrict as well and the frequency of the asthma attacks is reduced. The procedure is performed during bronchoscopy under moderate sedation or light anesthesia and is minimally invasive. The procedure can be performed over three outpatient visits, with each visit treating a different area of the lungs. Patients continue to take their standard maintenance asthma medications (AAAAI, 2024).

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 2023. 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 low-dose ICS-formotorol, taken as-needed for relief of symptoms, and if needed, before exercise (for adults and adolescents)
- Step 3 is the use of a low-dose ICS-formotorol maintenance and reliever therapy (adults and

adolescents)Step 4 is the use of a medium-dose ICS-formotorol maintenance and reliever therapy (adults and adolescents)Step 5 refer for expert assessment, phenotyping, and add-on therapy (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 (GINA, 2023).

The GINA Report also advises that caution should be used in selecting individuals for bronchial thermoplasty, and 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 (GINA, 2023).

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 the *Informational* section (*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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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

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℠ contract.

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