

Subject: Bronchial Thermoplasty

Background: Bronchial thermoplasty is proposed as a treatment option for adults whose severe persistent asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. The treatment consists of radiofrequency energy delivered to the distal airways with the aim of decreasing smooth muscle mass believed to be associated with airway inflammation.

Authorization: Prior authorization is required for all bronchial thermoplasty treatment requested for members enrolled in commercial (HMO, POS, or PPO) products.

- Initial authorization is limited to 3 treatment sessions with a recovery period of 3 weeks or longer between sessions.
- Requests for reauthorization, beyond the initial 3 treatments sessions, are considered experimental/investigational and unproven because the safety and efficacy of repeat procedures is not supported by published peer-reviewed literature.

This policy utilizes InterQual® criteria and/or tools, which Harvard Pilgrim may have customized. You may request authorization and complete the automated authorization questionnaire via HPHConnect at www.harvardpilgrim.org/providerportal. In some cases, clinical documentation and/or color photographs may be required to complete a medical necessity review. Please submit required documentation as follows:

- Clinical notes/written documentation —via HPHConnect Clinical Upload or secure fax (800-232-0816)
- Photographs— HPHConnect Clinical Upload function, email (utilization_requests@harvardpilgrim.org), or mail (Utilization Management, 1600 Crown Colony Dr., Quincy, MA 02169). Please note that photographs should not be faxed as faxed photos cannot be utilized in making a medical necessity determination.

Providers may view and print the medical necessity criteria and questionnaire via HPHConnect for providers (Select Resources and the InterQual® link) or contact the commercial Provider Service Center at 800-708-4414. (To register for HPHConnect, follow the [instructions here](#).) Members may access these materials by logging into their online account (visit www.harvardpilgrim.org, click on Member Login, then Plan Details, Prior Authorization for Care, and the link to clinical criteria) or by calling Member Services at 888-333-4742.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers bronchial thermoplasty as reasonable and medically necessary, for a maximum of three treatment session with a recovery period of three weeks or longer between sessions, in members with chronic, severe persistent asthma, as defined by lung function tests 60% or less of predicted value, and when documentation confirms ALL the following:

- Member has severe persistent asthma with forced expiratory volume in one second (FEV1) > 50 and <60% predicted; AND
- Member has severe persistent asthma as defined by ALL of the following despite appropriate use of asthma controller medications:
 - Daily symptoms of coughing, wheezing, shortness of breath; AND
 - Nighttime symptoms occur every night; AND

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- Daily physical activities are extremely limited.
- Member has chronic, severe persistent asthma that has been managed by an asthma specialist for at least 6 months; AND
- Documentation confirms at least ONE of the following:
 - Current use of inhaled corticosteroids and long-acting beta agonists or leukotrine inhibitors for at least 6 months, OR
 - Treatment has not been effective or tolerated, as evidenced by 2 or more exacerbations requiring oral corticosteroids in 12 months, OR member is taking or is being considered for chronic oral corticosteroids to maintain asthma control.
- Member is managed by a pulmonologist who has completed a bronchial thermoplasty training curriculum; AND
- Member is 18 years of age or older; AND
- Member is a non-smoker.

Exclusions: Harvard Pilgrim Health Care (HPHC) considers bronchial thermoplasty as experimental and investigational for all other indications. In addition, HPHC does not cover:

- Members with presence of a pacemaker, internal defibrillator, or other implantable electronic device
- Members with known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine and benzodiazepines
- Members with active respiratory infection
- Members with asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days
- Members with known coagulopathy
- Members previously treated prior to full course of bronchial thermoplasty (i.e., no more than 3 treatment sessions with a recovery period of 3 weeks or longer between sessions)

Supporting Information:

Bronchial thermoplasty (BT) (Alair® Bronchial Thermoplasty System, Asthmatx Inc.) is designed to weaken and partially destroy the smooth muscle that constricts the airway during asthma attacks. This procedure relies on a catheter that has an expandable array of electrodes and that has a fiber optic camera which allows the physician to see inside the lung. After the catheter is threaded into the airway, a wire leading out of the back end of the catheter is attached to a radiofrequency generator and the surgeon pulls a lever that causes the electrodes to curl into a ball shape around the front end of the catheter. The curved electrodes are held against the bronchial walls and an electrical current is applied to generate heat that destroys the smooth muscle beneath the lining of the bronchial passages. To simplify the process, the generator is programmed to deliver a controlled amount of energy, and it shuts off automatically in the presence of excessive energy delivery or tissue heating. The procedure is carried out in three outpatient visits, each one about 3 weeks apart. At the first visit, the airways of the right lower lobe are treated. The second, the left lower lobe, and the third treats both upper lobes.

Chupp et al. (2017) compared outcomes in bronchial thermoplasty subjects with a 3-year follow-up. 279 subjects were treated with bronchial thermoplasty in the post-market PAS2 (Post-FDA Approval Clinical Trial Evaluation Bronchial Thermoplasty in Severe Persistent Asthma) study. Results showed more PAS2 subjects experienced severe exacerbations (74% vs. 52%) and hospitalizations (15.3% to 4.2%) in the 12 months prior to bronchial thermoplasty. After 3 years of treatment, the percentage of PAS2 subjects with severe exacerbations, emergency department visits and hospitalizations significantly decreased by 45%, 55% and 50%, respectively.

Hayes, Inc (2016) published a medical technology directory report on bronchial thermoplasty for the treatment of asthma. They concluded that a small body of low-quality evidence suggests that during the first year after

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thermoplasty, benefits were observed, including improved quality of life, symptom relief, reduced medication use, and reductions in emergency department visits. Bronchial thermoplasty did not reduce hospitalizations following treatment and there was no evidence of improved lung function. Although preliminary evidence suggests that this treatment poses little long-term safety risk, there is insufficient evidence concerning the long-term safety and efficacy of bronchial thermoplasty.

Denner et al (2015) examined the presence of bronchoalveolar lavage cytokines and expression of smooth muscle actin in 11 patients with severe asthma before and in the weeks following BT. Bronchoalveolar lavage samples were collected from the right lower lobe before and 3 and 6 weeks after initial BT. Samples were analyzed for cell proportions and cytokine concentrations in bronchoalveolar lavage and for the presence of α -SMA in endobronchial biopsies. The results showed that α -SMA expression was decreased in endobronchial biopsies of 7 of 11 patients by week 6. In bronchoalveolar lavage fluid, transforming growth factor- β 1 and regulated upon activation, normal T-cell expressed and secreted (RANTES)/CCL5 were substantially decreased 3 and 6 weeks post BT in all patients. Cytokine tumor-necrosis-factor-related apoptosis-inducing ligand (TRAIL), which induces apoptosis in several cell types, was increased in concentration both 3 and 6 weeks post BT. The authors concluded that clinical improvement and reduction in α -SMA after BT in severe, uncontrolled asthma is associated with substantial changes in key mediators of inflammation. The data confirm the substantial elimination of airway smooth muscle post thermoplasty in the human asthmatic airway and represent the first characterization of significant changes in airway inflammation in the first weeks after BT.

Chakir et al (2015) evaluated the effects of BT on airway smooth muscle mass and airway collagen deposition in 17 adult patients with asthma, regardless of smooth muscle area. Patients underwent BT over the course of 3 visits. Bronchial biopsies were taken from the lower lobe that was not treated during that session at visit 1. Bronchial biopsies were taken from the lower lobe treated during the first session at visit 2 (3-14 weeks after the initial visit). At visit 3 (7-22 weeks after the initial visit), 9 of the 17 patients underwent biopsy of the same lower lobe biopsied during visit 2. Biopsy specimens underwent histological and immunohistochemical analysis. The results showed a significant decrease in airway smooth muscle at visit 2 and visit 3 compared to visit 1. BT also resulted in a significant decrease in Type I collagen deposition underneath the basement membrane at visit 2 and visit 3 compared to baseline. There was a significant improvement in asthma control, number of severe exacerbations, and doses of inhaled corticosteroid over the course of 1 year after BT. The authors concluded that for patients with severe asthma, BT reduced smooth muscle mass of treated airway segments, regardless of baseline level of muscle mass. BT also altered the deposition of collagen. BT improved asthma control at follow-up, however, correlations could not be evaluated due to the limited number of patients. Further studies are needed.

Heinen et al. (2014) reported that preliminary studies show good tolerance and some good efficacy in the use of BT to treat severe asthmatic patients. The authors reported that BT is an innovative treatment and more studies are needed to better understand its mechanism of action and more clearly delineate the precise indications of the technique.

A 2014 Cochrane review by Torrego et al. looked at studies to determine the efficacy and safety of bronchial thermoplasty in adults with bronchial asthma. Three RCTs were included in the review. Reviewers found BT provided a modest clinical benefit in quality of life and lower rates of asthma exacerbation, but no significant difference in asthma control scores. The reviewers also noted further research should provide the mechanisms of action of bronchial thermoplasty.

Dombret et al. (2014) assessed and reviewed studies and evidence for BT. The authors noted in their article, "Currently, the mechanisms of action for bronchial thermoplasty are poorly understood. Aside from the issue of

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reduced ASM mass, many questions remain (see online supplementary material for a list). None of the potential mechanisms mentioned have been studied either in preclinical experimental models of asthma or in clinical studies, and more work is needed in order to elucidate the various potential mechanisms of action of bronchial thermoplasty. Ultimately, this understanding may allow for improved appropriate patient selection.”

Wechsler et al (2013) assessed the effectiveness and safety of BT in asthmatic patients 5 years after therapy. BT-treated patients were evaluated annually for 5 years to assess the long-term safety and the durability of treatment effect of BT. Outcomes assessed included severe exacerbations, adverse events, health care use, spirometric data, and high-resolution computed tomographic scans. Out of 190 BT-treated patients enrolled in the study, 162 patients completed the 5-year follow-up. The results showed an average reduction of 44% in severe exacerbations and average reduction of 78% in emergency department visits following BT compared to the 12 months before BT. Compared with the first year after BT, respiratory adverse events and respiratory-related hospitalizations remained unchanged in years 2 through 5. Prebronchodilator FEV₁ values remained stable between years 1 and 5 following BT, despite an 18% reduction in average daily inhaled corticosteroid dose. High-resolution computed tomographic scans from baseline to 5 years after BT showed no structural abnormalities that could be attributed to BT. The authors concluded that the data demonstrate the 5-year durability of the benefits of BT with regard to both asthma control and safety.

Wahidi and Kraft (2012) reviewed available studies for BT and concluded proper patient selection and optimal pre- and post-procedural management are essential for a successful outcome. They noted further studies are needed to determine the durability of clinical effects, assess long-term adverse events, and better understand the mechanism of BT on asthma pathobiology.

Thomson et al. (2012) reviewed BT for severe asthma and found studies show fewer severe exacerbations and ER visits, but there is a short-term increase in asthma related morbidity. The authors felt the procedure has a role in the management of patients with severe asthma but future studies need to identify factors that predict a beneficial clinical response.

In the Thomson et al (2011) study, patients were enrolled in the Asthma Intervention Research Trial where they inhaled corticosteroids ≥ 200 μ g beclomethasone or equivalent and long-acting beta agonists. Out of the 52 treated, 45 participated in long-term follow-up and the rate of respiratory adverse events was stable in years 2 to 5, following bronchial thermoplasty. There was no increase in hospitalizations or emergency room visits for respiratory symptoms in years 2-5 as compared to year 1. The absence of clinical complications based on adverse events reporting and the maintenance of stable lung function over a 5-year period post bronchial thermoplasty treatment support the long-term safety and efficacy of the procedure.

Castro et al. (2011) reported results of patients from the AIR2 trial up to two years post-treatment. The primary endpoint was the comparison of proportion of thermoplasty patients experiencing severe exacerbations in year two compared with year one, post-treatment. 181 individuals were evaluated at year one, 166 at year two. Analysis showed the benefits of BT seen at year one was maintained at year 2.

Wu et al. (2011) conducted a meta-analysis to measure the efficacy and safety of bronchial thermoplasty for individuals with moderate-to-severe persistent asthma. They identified three randomized controlled trials (RCT) through an electronic literature search to assess outcomes of interest, such as Asthma Quality of Life Questionnaire (AQLQ) score, morning peak expiratory flow (PEF), tolerability and safety. The meta-analysis demonstrated a clear effect of bronchial thermoplasty yielding larger PEF improvements and on improving the asthma-specific quality of life over 1 year. In conclusion, the treatments were statistically significant and confirmed sustainable bronchodilatory effect of BT.

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A review by Rubin and Cardoso (2010) found bronchial thermoplasty to still be an experimental procedure. Their review of the available evidence indicated its main use will be in patients with severe, persistent asthma and difficult-to-control asthma, for whom, despite optimized treatment based on current guidelines, control cannot be achieved. It is not yet clear what subgroup of patients with severe asthma will most benefit from the procedure. The authors note it is also important to determine which patients the treatment should be contraindicated, due to low efficacy or potential adverse effects.

Castro et al. (2010) published a randomized, double-blind, sham-controlled study of bronchial thermoplasty (BT) in patients with severe asthma. 190 subjects were randomized and underwent at least 1 BT treatment. 98 subjects were randomized to the sham arm of the study and underwent at least 1 bronchoscopy. Follow up results were reported at 6 and 12 weeks, 6, 9 and 12 months. The primary outcome measure was the difference in Asthma Quality of Life Questionnaire (AQLQ). Adverse events and health care use were also collected to assess safety. Castro et al. reported a significant improvement in AQLQ scores in patients treated with BT. However, significant improvements in AQLQ scores were also seen in the sham patients. Secondary outcome measures did not show a difference between BT and sham procedures (Bel, 2010). Bel also noted in the editorial accompanying the published study, "Bronchial thermoplasty appears to have a benefit on the quality of life and severe exacerbations. Importantly, severe asthma has many phenotypes, and at present we have no clue which phenotype will benefit the most. It is inevitable that phenotypic targeting will be essential for this invasive procedure. Moreover, we need to know how durable the benefit will be to ensure that the benefits outweigh the risks and burden of the procedure. Therefore, long-term clinical and morphological research in various severe-asthma phenotypes is still needed to obtain the required information for clinical decisions."

Cox et al. (2007) reported on results of 109 asthmatic patients who were randomized to either a BT group or a control. 55 patients were treated with BT as an adjunct to drug therapy, 53 patients were randomized to the control group treated with corticosteroids. At 12 months, Cox et al. reported the BT group had significant improvements in mean change in AQLQ scores, mean morning peak expiratory flow, and mean change in ACQ score compared to control patients. Also at 12 months, there was no significant difference between the two groups in mean numbers of severe exacerbations of asthma, airway responsiveness, or forced expiratory flow in 1 second. Results also showed that BT was associated with significant increases in dyspnea, wheezing, chest discomfort, night awakenings, sputum discoloration, cough, and productive cough. However, there was no significant difference between the BT and control group in specific adverse events in the post-treatment period. A 2006 uncontrolled study of BT as an adjunct to standard drug therapy for mild-to-moderate asthma was reported by Cox et al. 16 patients underwent BT to assess the safety and impact on lung function and airway responsiveness over 2 years post-treatment. Patients had follow-up measures recorded at 12-week, 1 year and 2 years post treatment. Cox et al. found the procedure to be well tolerated, with side effects transient and typical of those commonly observed after bronchoscopy. All patients demonstrated improvement in airway responsiveness. At 12 weeks, significant improvement was seen in mean morning peak expiratory flow, and mean fraction of symptom-free days. No significant changes were seen in mean use of rescue medication at 12 weeks. Cox et al. concluded BT is well tolerated in patients with asthma and results in decreased airway hyper-responsiveness persisting for at least 2 years.

Pavord et al. (2007) reported on results of a clinical trial of BT in patients with symptomatic, severe asthma. 32 patients were randomized to a BT group that underwent the procedure as an adjunct to drug therapy. 17 patients were randomized to a control group undergoing drug therapy alone. At baseline, all patients were symptomatic despite treatment with fluticasone or equivalent and other meds. After treatment, all patients entered a 16-week steroid stable phase, a 14-week steroid wear phase, and a 16-week reduced steroid phase. At 52 weeks, compared to the control group, the BT group had significant improvements in mean rescue medication use, mean

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change in AQLQ score, and mean change in ACQ score. BT was associated with a short-term increase in asthma-related morbidity. However, there were no significant differences between the BT and control groups in adverse events during the post-treatment period.

In a review funded by Asthmatx, Inc., Cox et al. (2009) analyzed 3-year follow-up data from the Feasibility (Cox et al., 2006), AIR (Cox et al., 2007), and RISA (Pavord et al., 2007) trials. Analysis showed the number of respiratory-related adverse events per bronchoscopy was similar across all 3 studies following BT, but the distribution showed increasing severity of adverse events in patients with more severe asthma. Beyond the treatment period, review of asthma symptoms and the number and severity of patient-reported respiratory-related adverse events suggests patients remained stable post BT over the 3-year period. No deterioration in pulmonary function over three years was noted. Cox et al. concluded the absence of significant clinical complications and presence of stable lung function over a three-year period following BT, suggest that BT has a satisfactory long-term safety profile. While the trials indicated bronchial thermoplasty treatment can lead to significant improvements in AQLQ score and some secondary outcomes, there was also a significant placebo effect in patients treated in the AIR2 trial (Cox et al, 2010). Ideal patient selection criteria have not been established. Longer follow up data and additional randomized, sham-controlled trials are needed to further validate the benefits of BT on asthma patients' net health outcomes.

Guidelines:

A 2015 position statement by the American College of Allergy, Asthma, and Immunology (ACAAI) states that the scientific literature supports bronchial thermoplasty as a therapeutic consideration for some carefully chosen patients with severe asthma. They state that 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 insurers provide coverage of bronchial thermoplasty for those adult patients who meet the stringent requirements.

A 2014 position statement by the American College of Chest Physicians states that they believe literature supports bronchial thermoplasty as a therapeutic option for patients with severe asthma. They recommend that all public and private insurers provide coverage and payment for bronchial thermoplasty for those adult patients with severe, persistent, poorly-controlled asthma who continue to experience asthma exacerbations, emergency department visits and hospitalizations despite maximal medical treatment.

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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

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

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Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

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Summary of Changes

Date	Change
7/21	Annual review; no changes
8/20	Annual review; no changes
9/19	Annual review; no changes
4/19	No changes; Policy automated through InterQual®
2/18	Annual review; policy coverage criteria refined
2/17	Policy coverage criteria revised from non-coverage to medically necessary.

Approved by Medical Policy Committee: 7/6/21

Approved by Clinical Policy Operational Committee: 2/17; 2/18; 4/19; 9/19; 8/20; 7/21

Policy Effective Date: 7/26/21

Initiated: 2/17

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