Bronchial Thermoplasty (for Kentucky Only)

Policy Number: CS014KY.05
Effective Date: November 1, 2024

➲ Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Bronchial thermoplasty is unproven and not medically necessary for treating asthma due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

Description of Services

Asthma is a heterogeneous disease usually characterized by chronic airway inflammation. The symptoms of asthma include wheezing, shortness of breath, chest tightness, and/or cough. These symptoms may vary over time and in intensity, together with expiratory airflow limitation. The treatment for asthma includes a stepwise approach for symptom control with medications. Maintenance medications, including inhaled corticosteroids (ICS), ICS in combination with a long-acting beta$_2$-agonists, and leukotriene receptor antagonists, may help reduce airway inflammation and prevent asthma symptoms. Add-on maintenance medications include long-acting muscarinic antagonists, biologics, and systemic corticosteroids. Reliever medications may provide quick relief of asthma flare-ups (exacerbations) or prevent exercise-induced asthma symptoms. Anti-inflammatory relievers include low-dose combination ICS-formoterol and low-dose

combination ICS-short-acting beta$_2$-agonists (SABA). Bronchodilator relievers include SABA and short-acting anticholinergics (Global Initiative for Asthma, 2024).

Bronchial thermoplasty (BT) is a procedure intended for treating adults with severe persistent asthma that is not well controlled with conventional medications. BT is a minimally invasive, outpatient procedure that uses thermal radiofrequency (RF) energy to reduce airway smooth muscle (ASM) mass and responsiveness. In turn, this may reduce airway constriction and the severity and frequency of asthma symptoms. BT is administered at three outpatient visits about three weeks apart. The BT procedure is performed using a standard flexible bronchoscope which is introduced through the nose or mouth and into the lungs. A specialized catheter is advanced through the bronchoscope until it contacts the targeted airway wall. Controlled thermal RF energy is then delivered to the ASM while leaving the surrounding tissue undamaged (ECRI, 2020).

Clinical Evidence

Conclusive quality evidence is lacking to support the safety and efficacy of bronchial thermoplasty (BT) in the control of severe asthma. Retrospective studies of BT have shown variable results with less efficacy for individuals older than 65 years of age and higher body mass index (BMI). BT is non-inferior to biologicals in quality of life (QOL) and differences may exist due to the heterogeneity of the cohort populations used in studies. Moreover, there are concerns that some studies included individuals with less severe asthma and discordant correlation with clinical observations. Thus, the positive outcomes and biased QOL scores observed in these studies may not be applicable to individuals with severe asthma. Further randomized controlled trials (RCTs) are needed to determine the durability of clinical effects, assess long-term adverse events (AEs), and further understand the mechanism of BT on asthma.

Akaba et al. (2023) applied a self-controlled case series (SCCS) design to evaluate changes in the composite outcome of hospital admissions and emergency department (ED) visits due to asthma exacerbations between one year before and after BT. Changes in the amount of total-systemic corticosteroid exposure per person-year were also evaluated. The study included data from 102 adult patients with at least one ED visit or hospital admission, collected from a database of 561 patients who underwent BT at approximately 250 hospitals across Japan. The study results revealed that BT was significantly associated with an improvement in the composite outcome of hospital admission and ED visits (incidence rate ratio 0.53; 95% confidence interval [CI] 0.44-0.64). Systemic corticosteroid use was also reduced after BT (1931.5 mg to 641.3 mg per person-year; $p < .001$). Though, BT tended to be less effective among people older than 65 years and those with higher BMI. The authors concluded that this study, using real-world data, suggested BT may improve asthma control. However, BT effectiveness can vary depending on patient baseline profiles. Limitations of the study include the retrospective SCCS design and information available from the database.

Fong et al. (2023) conducted a systematic review and network meta-analysis (NMA) to examine if BT compares favorably with U.S. Food and Drug Administration (FDA) approved biological therapies for use in severe asthma, and to generate probability-based rankings of safety and efficacy. The review included 29 RCTs and 15,547 patients. (No RCT included in the NMA directly compared BT to biologics.) The results of the NMA revealed that fewer patients treated with BT experienced ≥ one asthma exacerbation compared to control. The annual exacerbation rate ratio of BT versus control was non-significant. Significant improvements in QOL, morning peak expiratory flow (PEF) rate, and oral corticosteroid dose reduction (OCDR) were found. No significant differences between BT and biologics were seen across indirect comparisons of all studies. The authors concluded that despite the lack of head-to-head comparative trials, the NMA suggests BT is non-inferior to biologics in terms of QOL. BT may also be noninferior for the outcomes of exacerbation rate reduction, lung function improvement, and OCDR. BT is a promising alternative for patients with severe asthma. Recommendations for future BT clinical trials included biomarkers or direct comparison with biologics to enrich current evidence. Limitations of the NMA included the absence of individual patient data, difficulty assessing methodological equivalence, and differences in patient selection criteria across studies.

Hatch et al. (2023) evaluated the safety and efficacy of BT five years post-procedure in a real-world cohort of patients with severe asthma. The study included 51 patients enrolled in a registry and treated with BT at two Australian tertiary centers. Five years post-procedure, patients were evaluated by interview, record review, Asthma Control Questionnaire (ACQ), spirometry, and high-resolution chest computed tomography (CT). The results of the study revealed significant improvements in ACQ from baseline (3.0 ±1.0) to 60 months later (1.8 ±1.0) ($p < 0.001$). Seventy-six percent of patients responded to BT with a fall in ACQ of 0.5 units or greater. Of the 13 patients in whom the ACQ had not improved by 0.5 units, the ACQ improved by 0.4 units in five patients. The remaining eight patients demonstrated no change in ACQ at 60 months. Per annum steroid requiring exacerbation frequency was also reduced from baseline (3.8 ±3.6) to 60 months later (1.0 ±1.6) ($p < 0.001$). Forty-four percent of patients weaned off oral steroids. A greater than 50% reduction in the requirement for reliever medications was also noted. There were no changes in spirometry observed. Minor degrees of localized radiological bronchiectasis were observed on CT for 23/47 patients. (Four patients were noted as unavailable to

undergo CT). Modified Reiff scores increased from baseline (0.6 ±2.6) to five years after BT (1.3 ±2.5) ($p < 0.001$). However, no patients exhibited features of clinical bronchiectasis. The authors concluded a sustained clinical benefit from BT at five years was demonstrated in this cohort of patients with severe asthma. While radiological bronchiectasis was noted on CT, it did not appear to be inducing clinical disease. Limitations of the study include a lack of randomization.

Nishi et al. (2023) conducted a retrospective case series on patients with severe asthma who underwent BT at a single institution in Japan. The study included clinical data for 21 patients recorded at the last visit before BT (baseline assessment) and at 12 months after BT (follow-up assessment). At the follow-up assessment, the study results revealed Asthma Quality of Life Questionnaire (AQLQ) scores ($p = 0.003$), maintenance oral corticosteroids (OCS) ($p = 0.027$), and exacerbation frequency ($p = 0.017$) significantly improved. Prebronchodilator forced expiratory volume in one second (FEV1) (% predicted) did not significantly change ($p = 0.19$). Additionally, when patients were grouped according to their BMI, AQLQ scores were more improved in patients with overweight/obesity than those with normal weight ($p = 0.01$). The authors concluded that patients with non-controlled severe asthma exhibiting overweight/obesity and low QOL had potential benefits from BT. The study findings are limited by small sample size and lack of contemporary comparison group.

Hayes completed a health technology assessment that focused on the use of BT as an adjunct treatment for severe, persistent asthma in adults that remain symptomatic despite medical management with inhaled corticosteroids (ICS) and long-acting beta$_2$-agonists (LABA). The assessment included 18 publications reporting on 15 studies. The results of the assessment revealed BT may reduce asthma exacerbations, healthcare utilization, and medication usage in patients with severe asthma. BT may also improve symptom control and asthma-related QOL. The improvements observed in symptom control and QOL were generally clinically significant. The benefits of BT were also generally sustained. BT did not improve pulmonary function measurements. During the BT treatment period, AEs were common. Hayes determined the overall body of evidence for BT was considered to be of “low-quality.” The studies included one “good-quality” RCT, three “fair-quality” RCTs, two “poor-quality” RCTs, two “poor-quality” comparative cohort studies, two “poor-quality” pretest-posttest studies, and five registry-based studies of “poor to very poor” quality. Hayes also noted there were individual study limitations, some inconsistency in findings for several outcomes, and limited evidence comparing BT with clinical alternatives. Future studies are needed to determine which patients with severe asthma are most likely to benefit from BT. Studies are also needed that compare the effectiveness of BT with other add-on treatments, including biologics (Hayes, 2022; annual review, 2023).

Chupp et al. (2022) conducted a prospective, open-label, observational, multicenter, single-arm study to analyze the five-year efficacy and safety results of BT in patients with severe asthma. The analysis included 227/284 subjects (80%) who completed five years of follow-up in the Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma (PAS2). The study results revealed that by year five, the proportion of subjects with severe exacerbations, ED visits, and hospitalizations was 42.7%, 7.9%, and 4.8% posttreatment, respectively. This was compared with 77.8%, 29.4%, and 16.1% in the 12 months prior to treatment. The proportion of subjects on maintenance OCS also decreased from 19.4% at baseline to 9.7% at five years. Additionally, a subgroup analysis, based on baseline clinical and biomarker characteristics, revealed a statistically significant clinical improvement among all subgroups. The authors concluded, five years after treatment, subjects in a PAS2 experienced decreases in severe exacerbations, hospitalizations, ED visits, and corticosteroid exposure. All subgroups also demonstrated clinically significant improvement, suggesting that BT improves asthma control in different asthma phenotypes. Limitations of the study include no sham or control group, subjects were not followed for the entire five years which introduced bias, and no comparison was done in response after BT, to responses to biological medications. (This study is included in the Hayes health technology assessment.)

Menzella et al. (2021) conducted a retrospective, observational study to compare patients diagnosed with severe refractory asthma (SRA) who are currently being treated with omalizumab, mepolizumab, benralizumab or BT and to evaluate the efficacy of these treatments over a 12-month observation period. The study included 199 patients, older than age 12, from a single center. The study results revealed a 16.7% reduction in hospitalizations, a 66.6% reduction in exacerbations ($p = 0.0001$), and the greater improvement in FEV1 (+ 37.4%, $p < 0.0001$) in patients treated with benralizumab (n = 32). There was an 85.7% reduction in hospitalizations ($p = 0.012$) and an 88.8% reduction in exacerbations ($p < 0.0001$) in patients treated with omalizumab (n = 54). There was an 89.5% reduction in hospitalizations ($p = 0.02$) and a 92.1% reduction in exacerbations ($p < 0.0001$) in patients treated with mepolizumab (n = 83). There was a 93.7% reduction in hospitalizations ($p = 0.001$) and a 73.5% reduction in exacerbations ($p < 0.0001$) in patients treated with BT (n = 30). Patients treated with BT and mepolizumab showed the best OCS sparing effect, -76% ($p < 0.0001$) and -90.2% ($p = 0.002$), respectively. The authors concluded that all biologics, to varying degrees, reduced hospitalizations, exacerbations, and usage of OCS. Additionally, despite a starting point for patients in the BT group that was worse for hospitalizations, exacerbations, and usage of OCS, BT obtained positive results that was comparable to biologics. The

study is limited by lack of randomization to the various treatment groups or comparison to sham procedure. (This study is included in the Hayes 2022 Health Technology Assessment.)

Chaudhuri et al. (2021) conducted an international, multicenter, prospective study to investigate the efficacy and safety of BT after ten or more years of follow-up. The Bronchial Thermoplasty 10+ Year Study (BT10+) enrolled 192 (45%) of the 429 participants who were previously enrolled in the Asthma Intervention Research (AIR), Asthma Intervention Research-2 (AIR2), and Research in Severe Asthma (RISA) RCTs. Of the total, BT10+ included 136 participants who received BT (52% of the 260 participants who received BT in the original trials), and 56 participants randomized to sham or control (33% of the 169 participants from the original trials). (Eighteen participants randomized to sham or control received BT after the AIR, AIR2, and RISA trials concluded.) BT10+ participants were followed for 10.8-15.6 years (median 12.1 years) post-treatment. Endpoint and other data for BT10+ were collected at a ten-year outcomes study visit. The study results revealed that participants treated with BT had similar proportions of severe asthma exacerbations at the BT10+ visit compared with one year and five years after treatment. QOL and spirometry measurements for were similar between year one, year five, and the BT10+ visit. A reduction in hospital ED visits and hospital admissions for asthma was observed for patients treated with BT. Pulmonary high-resolution CT scans from AIR2 participants treated with BT showed that 13 (13%) of 97 participants had bronchiectasis at the BT10+ visit. (Only AIR2 participants underwent CT imaging at baseline.) Six (7%) of 89 participants treated with BT who did not have bronchiectasis at baseline developed bronchiectasis after treatment. (Five participants were classified as having mild bronchiectasis and one participant was classified as having moderate bronchiectasis.) Participants in the control group were also noted to have had decreases in severe asthma exacerbations, hospital ED visits, and hospital admissions. The authors concluded that the efficacy and safety of BT is sustained for 10 or more years. BT is a long-acting therapeutic option for patients with uncontrolled asthma despite optimized medical treatment. However, the BT10+ study has some limitations. Several participants from the original AIR, AIR2, and RISA studies were not enrolled into BT10+ due to lost to follow-up. The reporting of results pertaining to severe asthma exacerbations was based on patient recollection supported by case note reviews by investigators. The study was funded by the manufacturer of the BT system and three of the authors are full-time employees of the manufacturer, which could potentially lead to a conflict of interest. Additionally, the study is limited by differential loss-to-follow-up between sham and active group and cross-over to the active group. Furthermore, the main findings on which the conclusions are made are based on the active group persistence of effect over time (case series design) rather than on a comparison with the sham group. The authors also recommended caution when interpreting the asthma control improvements observed in the BT10+ study. These improvements might not be applicable to patients with the most severe asthma who are seen in clinical practice, as 26% of BT10+ participants did not have severe asthma. (This study is included in Fong et al., 2023 and the Hayes health technology assessment.)

Goorsenberg et al. (2021) conducted an international, multicenter RCT to assess the effects of BT on airway smooth muscle (ASM) mass and to identify characteristics that correlate with response in patients with severe asthma. Prior to randomization, clinical, functional, blood, and airway biopsy data were collected. Forty patients were then randomized to immediate BT treatment (n = 20) or delayed BT treatment (n = 20) (control group). The delayed control group received BT after six months of standard clinical care. Both groups underwent BT treatment of right lower lobe, left lower lobe, and both upper lobes with at least a three-week interval between procedures. Post-BT data, including biopsies, were obtained after six months. The study results revealed median ASM mass decreased by > 50% in the immediate BT group versus no change in the delayed control group (p = 0.0004). In the immediate BT group, ACQ scores improved with 0.79 (interquartile range [IQR], 1.61 to 0.02) compared with 0.09 (IQR, 0.25 to 1.17) in the delayed control group (p = 0.006). AQLQ scores improved with 0.83 (IQR, 0.15 to 1.69) versus 0.02 (IQR, 0.77 to 0.75) (p = 0.04). Treatment response in the total group was positively associated with serum immunoglobulin E (IgE) and eosinophils, but not with baseline ASM mass. The authors concluded ASM mass decreased significantly after BT when compared with a randomized non-BT control group. Treatment response was associated with serum IgE and eosinophil levels, but not with ASM mass, potentially adding important information to the selection of appropriate candidates for BT. The study is limited by lack of masking, which could have impacted prescription of additional therapies and responses to the subjective questionnaire, as well as a small sample size, which could have been insufficient to detect important AEs. Furthermore, the comparison between randomized arms was limited to six months. (This study is included in Fong et al., 2023 and the Hayes Health Technology Assessment).

Langton et al. (2020) conducted a small, prospective case series to evaluate the effects of BT, 12 months post-procedure, on airway volume in patients with severe asthma. The study included ten consecutive patients that needed to be using inhaled triple therapy, had poorly controlled symptoms, and with frequent exacerbations requiring oral steroids. Baseline data collection included ACQ and high-resolution CT at total lung capacity (TLC) and functional residual capacity (FRC). CT was repeated 4 weeks after the left lung was treated with BT, but prior to right lung treatment, and then again 12 months after both lungs were treated. Other outcome parameters, including ACQ and oral steroid-requiring exacerbations, were measured at 6- and 12-months post-BT. The study results revealed that ACQ improved from 3.4 ±1.0 to 1.5 ±0.9 (p = 0.001) 12 months post-PT. The frequency of oral steroid-requiring exacerbations also improved (p = 0.008). Total

airway volume increased 12 months after BT in both the TLC (p = 0.03) and the FRC scans (p = 0.02). No change was observed in airway volume for the untreated central airways. In the BT-treated distal airways, increases in airway volume of 38.4 ±31.8% at TLC (p = 0.03) and 30.0 ±24.8% at FRC (p = 0.01) were observed. The change in distal airway volume was correlated with the improvement in ACQ (r = -0.71, p = 0.02). The authors concluded that BT induces long-term increases in airway volume, which correlate with symptomatic improvement. This study is limited by a lack of comparison group and small sample size.

ECRI completed a clinical evidence assessment that focused on how well the Alair™ System (Boston Scientific Corp.) worked for treating severe asthma with BT in patients irresponsive to medications. The assessment included two systematic reviews and one prospective, nonrandomized, comparison study reporting on a total of 1,845 patients. The results of the assessment revealed that the reported benefits of the Alair are modest and of unclear clinical significance for asthma control, asthma exacerbation, reduced hospitalizations, and QOL up to one year. It was also unclear if the benefits were clinically significant or sustained beyond one year. AEs were more common with the Alair than with sham or standard medical therapy. ECRI concluded that the available clinical evidence for the Alair was inconclusive due to study limitations. One systematic review comparing BT to immunotherapy provided only indirect evidence because no head-to-head RCTs were available. The studies in both systematic reviews were at a risk of bias due to small sample size, lack of randomization, lack of blinding, and/or differences in follow-up times. Studies reported between-group differences of unclear significance because the results were imprecise for some outcomes. The findings may also not be generalizable because of differences in patient characteristics across studies. The comparison study is at a high risk of bias due to the small sample size, single-center focus, and lack of randomization. Larger, multicenter RCTs that report longer-term outcomes are needed to validate BT with the Alair (ECRI, 2020).

Burn et al. (2017) reported results from a retrospective study of BT procedural and short-term safety outcomes for routine United Kingdom (UK) clinical practice patients. Patient characteristics and safety outcomes were assessed using two independent data sources, the British Thoracic Society UK Difficult Asthma Registry and the Hospital Episodes Statistics database. A matched cohort of 59 patients involving 152 procedures at six centers was used to estimate safety outcome event rates compared with clinical trial results. Study results for the matched cohort revealed that procedural complications were reported in 17/152 procedures (11.2%; 13/59 patients); 18/152 procedures (11.8%; 15/59 patients) were followed by an emergency readmission within 30 days for respiratory cause; and 13/152 procedures (8.6%; 13/59 patients) were followed within 30 days by an accident and emergency (A&E) attendance admission for any cause. Overall, 31/152 procedures (20.4%) were associated with at least one safety issue within 30 days. Seventy of 152 procedures (46.1%) were followed by an overnight stay. Compared with published clinical trials, which found lower hospitalization rates, patients undergoing BT in routine clinical practice were, on average, older, had worse baseline lung function and asthma QOL. The authors concluded that a higher proportion of patients experienced AEs compared to clinical trials. However, the greater severity of disease in patients undergoing BT in routine clinical practice may explain the observed rate of post-procedural stay and readmission. The study findings are limited by lack of randomization. (This review is included in the Hayes Health Technology Assessment).

Chupp et al. (2017) published a comparison of three-year follow-up results from two prospective, multicenter studies of BT for subjects with severe asthma. The study compared the first 190 subjects enrolled in the post-marketing PAS2 trial with the 190 subjects treated with BT in the AIR2 RCT. The study results revealed that the percentage of subjects enrolled in PAS2 with severe exacerbations, ED visits, and hospitalizations at year three after BT, significantly decreased by 45%, 55% and 40%, respectively. The PAS2 results echoed the AIR2 results. Subjects enrolled in PAS2 and AIR2 were both able to significantly reduce their mean ICS daily dose. The percentage of subjects enrolled in PAS2 who were taking daily OCS to improve asthma control was reduced from 18.9% at baseline to 10.2% in the third year after BT. However, this decrease was not apparent in the AIR2 trial, where a lower percentage of the subjects who received BT were on maintenance OCS medication at baseline. Prebronchodilator FEV1 remained unchanged from baseline throughout the 3-year follow-up period. Postbronchodilator FEV1 remained higher than prebronchodilator values at all times. The authors concluded that PAS2 demonstrated similar improvements in asthma control after BT compared with the AIR2 trial despite enrolling subjects who may have had poorer asthma control. BT was safe, subjects had durable and markedly lower rates of steroid exacerbations, ED visits, and hospitalizations three years after BT. Limitations of the study include lack of comparison with a contemporary control group undergoing a different therapy.

Zhou et al. (2016) performed a systematic review and meta-analysis to evaluate the long-term efficacy and safety of BT in the treatment of patients with moderate to severe persistent asthma. The review included 249 subjects treated with BT who had one-year follow-up data and 216 subjects who had a five-year follow-up data from three RCTs and three extension studies. Outcomes assessed after BT included spirometric data, respiratory AEs, ED visits, and hospitalization for respiratory illness at a one year and five-year follow-up. The study results revealed no evidence of significant decline in prebronchodilator FEV1 or in postbronchodilator FEV1 between one year and five years. The frequency of respiratory AEs was reduced significantly during the follow-up. The number of ED visits for respiratory AEs remained unchanged after BT

treatment. There was no statistically significant increase in the incidence of hospitalization for respiratory AEs. The authors concluded that BT showed reasonable long-term safety and efficacy for moderate-to-severe asthmatic patients. However, a large-scale clinical study should be performed to confirm the finding. There are several limitations in this study. Almost all studies included in this meta-analysis did not have a control group (sham group) for the five-year follow-up. The authors stated that findings from current studies are based merely on clinical manifestations and outcomes. Histological assessment after BT could provide more evidence to support the findings. (This review is included in the Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment).

A Cochrane systematic review by Torrego et al. (2014) concluded, based on a review of the AIR, AIR2, and RISA RCTs (429 participants), that BT for patients with moderate to severe asthma provides a modest clinical benefit in QOL and lower rates of asthma exacerbation, but no significant difference in asthma control scores. The QOL findings were at risk of bias, as the main benefits were seen in the two studies that did not include a sham treatment arm. This procedure increases the risk of AEs during treatment, but has a reasonable safety profile after completion of the bronchoscopies. The overall quality of evidence regarding this procedure is moderate. Further research should provide better understanding of the mechanisms of action of BT, as well as its effect in different asthma phenotypes or in patients with worse lung function. (This review is included in the Hayes Health Technology Assessment and ECRI Clinical Evidence Assessment).

Wu et al. (2011) performed a meta-analysis to assess the safety and efficacy of BT in patients with moderate to severe asthma. The meta-analysis included three RCTs and 421 patients. The largest RCT included 288 patients and the smallest RCT included 32 patients. Two of the RCTs compared BT with standard asthma medications and one RCT compared BT with sham BT treatment plus standard asthma medications. The results of the meta-analysis revealed that compared with standard medications and sham treatment (combined), BT caused more respiratory AEs and hospitalizations, but most events resolved within a week. While the two RCTs that did not include a sham procedure appeared to show some benefits on QOL and PEF, these findings were not significant for the sham-controlled trial. The authors concluded, despite its preliminary nature and limitations, the meta-analysis demonstrated that compared with medications or sham, BT significantly improved PEF, QOL, and was generally well tolerated and safe. However, additional long-term RCTs are needed to confirm whether BT provides benefit to patients with moderate to severe persistent asthma. The authors noted several study limitations. All three RCTs provided asthma medications to patients in both the BT and control groups. The effects of BT on asthma independent of co-administered medications is not known. The sample size was limited by the three RCTs. The included RCTs were diverse both clinically and methodologically and some heterogeneity occurred in some of the analyses. The RCTs were underpowered to detect some outcomes of interest including FEV1, FEV1 % predicted, exacerbations, rescue-medication use, and the longer term (> one year) efficacy and safety of BT in moderate to severe persistent asthma. (This meta-analysis is included in the ECRI Clinical Evidence Assessment).

Clinical Practice Guidelines

American College of Chest Physicians (CHEST)

CHEST published a coverage and payment position statement that concluded, based on the strength of the clinical evidence, BT offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment (CHEST, 2014).

British Thoracic Society (BTS)

BTS guidelines on the management of asthma state“Bronchial thermoplasty may be considered for the treatment of adult patients (aged 18 and over) with severe asthma who have poorly controlled asthma despite optimal medical therapy” (Grade of recommendation: B).

- “Patients being considered for bronchial thermoplasty should be assessed to confirm the diagnosis of asthma, that uncontrolled asthma is the cause of their ongoing symptoms, and that they are adherent with current treatment.”
- “An asthma specialist with expertise in bronchial thermoplasty should assess patients prior to undergoing treatment, and treatment should take place in a specialist centre with the appropriate resources and training, including access to an intensive care unit.”
- “Patients undergoing bronchial thermoplasty should have their details entered onto the UK Severe Asthma Registry.”

“Further research is needed to identify which patients with asthma might benefit from bronchial thermoplasty. However, it is likely that patients who remain uncontrolled despite optimal medical treatment and who have been considered for biological treatments and are either unsuitable for or fail a trial of such a treatment may be an appropriate group, as other treatment options for these patients are elusive. There are no trials comparing the efficacy of bronchial thermoplasty with biological treatments for people with asthma” (BTS, 2019).

European Respiratory Society/American Thoracic Society (ERS/ATS)

ERS/ATS guidelines for the treatment of severe asthma recommend BT for adults only in the context of an independent systematic registry or a clinical study with institutional review board (IRB) approval (strong recommendation, very low-quality evidence). The guidelines note, “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. Both 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. Specifically designed studies are needed to define its effects on relevant objective primary outcomes such as exacerbation rates, and on long-term effects on lung function. Studies are also needed to better understand the phenotypes of responding patients, its effects in patients with severe obstructive asthma (FEV_1 < 60% of predicted value) or in whom systemic corticosteroids are used, and its long-term benefits and safety. Further research is likely to have an important impact on this recommendation” (Chung et al., 2014).

Global Initiative for Asthma (GINA)

GINA guidelines for asthma management and prevention state BT may be considered for some adults with severe asthma who remain uncontrolled despite optimized therapeutic regimens and referral to a specialty center. BT should only be performed as part of an independent IRB-approved systematic registry or clinical research study. Evidence for the efficacy and long-term safety of BT is limited and only in selected patients (Evidence level: B) (GINA, 2024).

National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC)/National Heart, Lung, and Blood Institute (NHLBI)

NAEPPCC/NHLBI asthma management guidelines state, "Most individuals ages 18 years and older with uncontrolled, moderate-to-severe, persistent asthma should not undergo BT to treat asthma because the benefits are small, the risks are moderate, and the long-term outcomes are uncertain. Some individuals with moderate-to-severe persistent asthma who have troublesome symptoms may be willing to accept the risks of BT and, therefore, might choose this intervention after shared decision-making with their health care provider. Clinicians should offer the procedure in the setting of a clinical trial or a registry study to enable the collection of long-term data on the use of BT for asthma." These guidelines are based on the AIR, AIR2, and RISA RCTs. Limitations of these three trials include funding by the company that markets the BT device, a lack of long-term follow-up, and an insufficient number of patients to fully assess clinical benefits and harms. Additional research that includes RCTs and long-term registry outcomes would be beneficial (NAEPPCC/NHLBI, 2020).

National Institute for Health and Care Excellence (NICE)

NICE interventional procedures guidance on BT for severe asthma states that the current safety and efficacy evidence is adequate to support the use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. However, BT should only be used for severe asthma that is uncontrolled despite optimal drug treatment. BT should only be performed by a multidisciplinary team in specialist centers with on-site access to intensive care. Additionally, BT should only be performed by clinicians with training in the procedure and experience managing severe asthma. There is uncertainty about which patients may benefit from BT. Future research should report the details of BT patient selection and long-term safety and efficacy outcomes (NICE, 2018).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on BT systems, refer to the following website (use product code OOY): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed May 22, 2024)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Supporting Information** • Updated *Description of Services, Clinical Evidence, FDA,* and *References* sections to reflect the most current information • Archived previous policy version CS014KY.04

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.