Bronchial Thermoplasty (for Kentucky Only)

Policy Number: CS014KY.04
Effective Date: January 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 and chronic disease characterized by variable symptoms such as wheeze, shortness of breath, chest tightness, and/or cough that vary over time and in intensity, together with variable expiratory airflow limitation (GINA

2023). Standard treatment approaches for asthma involve environmental control measures and avoidance of risk factors, plus comprehensive drug therapy. Long-term control medications, such as inhaled corticosteroids (ICS) or long-acting $beta_2$-agonists (LABA), long-acting muscarinic agents (LAMA), leukotriene antagonists, and biologics may help reduce airway inflammation and prevent asthma symptoms. Quick-relief medications, such as short-acting $beta_2$-agonists, relieve asthma symptoms that may cause flare of symptoms. Adding an (ICS) controller to daily treatment is often recommend to control exacerbations and symptoms.

Bronchial thermoplasty (BT) is a procedure intended for treating adults with severe persistent asthma that is not well controlled with conventional drug therapy. BT is a minimally invasive, outpatient procedure that uses thermal energy (radiofrequency) to reduce smooth muscle mass which in turn reducing airway constriction. and l may reduce the severity and frequency of asthma symptoms. The treatments are three outpatient visits over a three-week period. The BT procedure is performed using a standard flexible bronchoscope, which is introduced through the nose or mouth and into the lungs. The catheter tip has an expanded basket with four arms that enter in contact with the airway wall. A controlled thermal energy is then delivered to the airway walls to reduce excess smooth muscle tissue while leaving surrounding tissue undamaged (ECRI, 2020).

Clinical Evidence

Bronchial thermoplasty (BT) is a non-drug procedure used to treat adult patients with severe asthma who remain symptomatic despite adherence to conventional treatments. Conclusive quality evidence is lacking to support the safety and efficacy of BT in the control of severe asthma and asthma exacerbation. Further randomized control studies are needed to determine the durability of clinical effects, assess long-term adverse events, and further understand the mechanism of BT on asthma.

Akaba et al. (2023) applied a self-controlled case series design to evaluate changes in the composite outcome of hospital admissions and emergency department visits in patients with asthma exacerbations and outcomes of systemic corticosteroid use, between 1 year before and after BT. From the 561 patients with asthma who underwent BT treatment between September 2014 and March 2020, 102 patients with at least 1 outcome were analyzed. The authors stated that BT was significantly associated with an improvement in the composite outcome of hospital admission and emergency department visits (incidence rate ratio 0.53; 95% CI 0.44e-0.64); systemic corticosteroid use was reduced after BT sessions (1931.5 mg to 641.3 mg per person-year; $p < .001$); and BT tended to be less effective among people older than 65 years and those with higher body mass index. However, the effectiveness of BT can vary depending on patient baseline profiles such as BMI and age. Limitations identified in the study included possible residual confounding factors, a small sample size, BT outcomes may have been affected by pretreatment conditions, and disease duration may have affected treatment response to BT.

Nishi et al. (2023) conducted a retrospective and observational cohort analysis case series on patients with severe asthma who underwent BT at a single institution in Japan between September 2017 and October 2019. A total of 21 patients completed follow-up assessments using the Asthma Quality of Life Questionnaire (AQLQ). The authors' findings identified AQLQ scores ($p = 0.003$), maintenance oral corticosteroid doses ($p = 0.027$), and exacerbation frequency ($p = 0.017$) were improved, while prebronchodilator-forced expiratory volume in 1 second (% predicted) did not significantly change ($p = 0.19$). Additional findings according to BMI levels were reviewed by the authors. Patients were placed into 2 groups, normal weight versus overweight or obesity, identified according to their body mass index levels, the 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 quality of life had potential benefits from BT. The findings are limited by lack of contemporary comparison group.

Chupp et al. (2022) conducted a prospective, open-label, observational, multicenter single-arm study and analyzed the clinical outcomes over 5 years after BT treatment for the full cohort of 284 Post-FDA Approval Clinical Trial Evaluating BT in Severe Persistent Asthma (PAS2) subjects compared to the year before the intervention. Their findings by year 5 posttreatment, the proportion of subjects with severe exacerbations, ED visits, and hospitalizations was 42.7%, 7.9%, and 4.8%, respectively, compared with 77.8%, 29.4%, and 16.1% in the 12 months prior to treatment. The proportion of subjects on maintenance oral corticosteroids decreased from 19.4% at baseline to 9.7% at 5 years. The authors concluded, five years after treatment, subjects experienced decreases in severe exacerbations, hospitalizations, ED visits, and corticosteroid exposure. Additionally, the authors determined all subgroups demonstrated clinically significant improvement, suggesting that bronchial thermoplasty improves asthma control in different asthma phenotypes. Limitations in the study include no sham or control group, subjects were not followed for the entire 5 years which introduced bias, and no comparison was done in response after BT to responses to biological medications.

A Hayes Health Technology Assessment (2022) examined the efficacy of BT as an adjunctive treatment for symptomatic adults with severe persistent asthma despite medical management. The findings suggests that there are some short-term benefits of BT. However, due to a low-quality body of evidence further studies should seek to ascertain if patients with severe asthma would benefit from treatment and evaluate the comparisons of alternative treatments for severe persistent asthma, such as biologics. The health technology safety assessment does identify that BT was affiliated with more adverse events during the treatment period than sham treatment or medical management, but adverse events did not differ between groups after end of treatment. In addition, the usage of BT in treatment of mild to moderate asthma in adults was assessed. Hayes reports there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management at this time.

Menzella et al. (2021) conducted a retrospective, observational study to compare patients diagnosed with severe refractory asthma (SRA) who are currently being treated with monoclonal antibodies (mAbs) and BT. The study included 199 patients with SRA who were treated with omalizumab, mepolizumab, benralizumab or BT and the efficacy of these treatments over a 12-month observation period were evaluated. In this study population, patient's demographic and clinical characteristics were used to collect data. The authors' findings exhibited that the benralizumab group (32 patients), had a 16.7% reduction in hospitalizations, a 66.6% reduction in exacerbations ($p = 0.0001$) and an improvement in FEV1 (+ 37.4%, $p < 0.0001$). The 54 patients treated with omalizumab, had an 85.7% ($p = 0.012$) reduction in hospitalizations and an 88.8% ($p < 0.0001$) reduction in exacerbations. The mepolizumab group (83 patients), had an 89.5% ($p = 0.02$) reduction in hospitalizations and a 92.1% ($p < 0.0001$) reduction in exacerbations. The 30 patients treated with BT showed a 93.7% ($p = 0.001$) reduction in hospitalizations and a 73.5% ($p < 0.0001$) reduction in exacerbations. In addition, reduction in oral-corticosteroid (OCS) usage was found with the implementation of BT (- 76%, $p < 0.0001$) and mepolizumab (- 90.2%, $p = 0.002$). The authors' concluded that biologics and BT all reduced hospitalizations, exacerbations and OCS usage. They identified patients in the BT group starting point were worse regarding hospitalizations, exacerbations and OCS usage. Regardless, the BT results were positive in comparison to biologics. The study is limited by lack of randomization to the various treatment groups or comparison to sham procedure. (This review is included in the Hayes 2022 Health Technology Assessment).

Chaudhuri et al. (2021) conducted an international, multicenter prospective follow-up of three randomized control trials; the Asthma Intervention Research (AIR) trial, the Asthma Intervention Research-2 (AIR2) trial, and the Research in Severe Asthma (RISA) trial to determine safety and effectiveness outcomes of BT in patients with persistent asthma 10 + years (BT10+) after the procedure. The BT10+ study included 192 participants; 136 participants who received BT in the original trial and 56 sham or control participants of which 18 received BT after the previous study ended The follow-up was 10·8–15·6 years (median 12·1 years) post-treatment. A reduction in hospital emergency department visits and hospital admissions for asthma were observed. Quality of life measurements and spirometry were similar between year 1, year 5, and the BT10+ visit. Reductions in both the proportion of participants with severe exacerbations after BT and the number of severe exacerbations per participant appeared to be sustained for 10 years or more. The authors concluded the data from the BT10+ study showed efficacy and safety for those who underwent BT for 10 + years. The authors noted several study limitations. The length of time between participation in original trials and the BT10+, resulted in several participants not being included in the BT10+ study. 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. (This review is included in the Hayes 2022 Health Technology Assessment).

Goorsenberg et al. (2021) conducted an international-multicenter randomized control trial of 40 patients with severe asthma who underwent bronchial thermoplasty induced airway smooth muscle (ASM) reduction at enrollment or after a delay of six months. The aim was to assess the effects of BT on ASM mass in airways and to compare baseline and post BT. The outcomes were measured by Asthma Control Questionnaire (ACQ) and Asthma Quality of Life Questionnaire (AQLQ) results. Twenty patients received immediate BT treatment, and 20 (control group) received BT treatment 6 months later. Both groups underwent BT treatment of right lower lobe (RLL), left lower lobe (LLL) and then right upper lobe (RUL) and left upper lobe (LUL) within a three-week interval. The right middle lobe (RML) was not treated in all 40 patients. Patients underwent ASM biopsies prior to BT, during BT, from RML, and at six months post BT. Median ASM mass decreased by ≥ 50% in the immediate BT group versus no change in the control group ($p = 0.0004$). In the immediate group, Asthma Control Questionnaire 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 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) ($p = 0.04$). The authors concluded BT significantly reduces ASM mass in patients with severe asthma compared to the patients in the control group. They also identified ASM mass in the proximal parts of the untreated RML were improved as well. 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 adverse events. Furthermore, the comparison between randomized arms was limited to six months. Clinical trials.gov Identifier: NCT02225392. (This review is included in the Hayes 2022 Health Technology Assessment).

Langton et al. (2020) conducted a small prospective case series on the effect of BT 12 months post-procedure. The study included 10 patients with severe asthma who needed inhaled triple therapy and had poorly controlled symptoms with frequent exacerbations requiring oral steroids. Baseline data collected included an Asthma Control Questionnaire (ACQ), a high-resolution CT at total lung capacity (TLC) and a functional residual capacity (FRC). The ACQ score at baseline was 3.4 ±1.0 after left lung was treated 2.1 ±0.9, then 6 weeks after both lungs were treated 1.4 ±1.0 6 and 1.5 ±12 months post-procedure. The CT protocol was repeated 4 weeks after the left lung had been treated by BT, but prior to right lung treatment, and then again 12 months after both lungs were treated The TLC measured by CT scanning at baseline 4.91 ±1.55 L and at 12 months was 4.98 ±1.25 L. The FRC, the total lung volume at baseline was 3.63 ±1.12 L and at 12 months was 3.50 ±1.15 L. The authors concluded that BT induces long-term increases in airway volume, which correlate with symptomatic improvement, and the CT scan method at TLC is a promising tool for future objective evaluations of patient responses to BT. This study is limited by a lack of comparison group and small sample size.

An ECRI Clinical Evidence Assessment report on the Alair™ Bronchial Thermoplasty System for treating severe asthma focused on how well Alair works for treating severe asthma patients unresponsive to medications. The assessment reviewed clinical studies published between January 1, 2008 to May 12, 2020, identified two systematic reviews and 1 nonrandomized comparison study reporting on a total of 1,845 patients. The assessment concluded that Alair's reported benefits are modest and of unclear clinical significance for asthma control, asthma exacerbation, reduced hospitalizations, and quality of life (QOL) up to one year, based on these reviews. Adverse events (AEs) were more common with Alair than sham or standard medical therapy. The evidence was considered inconclusive and larger, multicenter RCTs that report longer-term outcomes are needed to validate BT with Alair (ECRI, April 2007; updated May 2020).

Qiu et al. (2020) conducted a retrospective study to analyze the data for radiologic and bronchoscopic changes in 12 patients who had severe asthma and had undergone BT. All 12 patients underwent a baseline chest x-ray or CT scan prior to the procedure. Within 24 hours of the procedures a total of 9 patients had symptoms including cough, expectoration, tachypnea, wheezing, chest tightness, chest pain and dyspnea. At 18-24 hours post BT, a total of 33 chest x-rays and one CT scan were collected. Radiological abnormalities were observed in 32 x-rays which included which included atelectasis (53.1%), peribronchial consolidations (84.4%), pleural effusion (18.8%), effusion in oblique fissures (3.1%), pleural thickening (6.3%) and pneumothorax (3.1%). At follow-up visits between 2-15 days after BT a total of seven patients developed tachypnea, chest tightness, chest pain, wheezing or dyspnea. At that time 23 bronchoscopic examinations were required which revealed phlegm plugs occluding the bronchus in the treated lobe. At follow-up 16-30 days post BT 95.7% of the chest x-ray issues were resolved, and no bronchoscopies were required. The authors concluded from this study that this is the first case of pneumothorax post BT that needed intubation and there is high incidence for early radiologic abnormalities and bronchial phlegm plugs.

A systematic review to assess the effectiveness and safety of BT in adults with asthma was conducted by D'Anci et al. (2017). Fifteen studies, including three randomized control trials (RCTs) with 5-year single-arm follow-up in BT-treated patients (n = 432), examined the impact of BT in addition to standard care (continued medical management) on patients with asthma. Compared with standard care, BT improved asthma control, health care utilization (defined by rescue medication use), and quality of life (low strength of evidence [SOE]). The clinical relevance of these findings is uncertain. Rates of mild exacerbations were reduced following BT (low SOE), but the clinical relevance was uncertain. The evidence base was insufficient to draw conclusions about BT's effects on severe exacerbations, FEV1, and airway hyper-responsiveness compared with standard care. Compared with sham treatment, BT had no effect on asthma control, hospitalizations for respiratory symptoms, health care utilization, pulmonary physiology measures, or other asthma symptoms outcomes (low SOE). Reduced risk of severe exacerbations was suggested (low SOE), although the clinical importance of this difference was unclear. BT was associated with fewer emergency department visits than sham treatment during the post-treatment period (moderate SOE). The evidence was inconclusive regarding quality-of-life scores following BT or sham (insufficient SOE). Serious adverse events attributed to BT were infrequent, and no deaths were reported. The authors concluded that based on the available literature, BT may be modestly beneficial in some patients with asthma but is not without risks. The risk of adverse events is higher early in treatment, while benefit is typically observed weeks to months after therapy and can last for at least 5 years, after which the effect is

unknown. (Publication by Thomson 2011, previously cited in this policy, is included in this systematic review). (This review is included in the Hayes 2022 Health Technology Assessment and ECRI 2020 Clinical Evidence Assessment).

Burn et al. (2017) reported results of a retrospective study of procedural and short-term safety outcomes for routine United Kingdom (UK) clinical practice patients who underwent BT. They assessed safety outcomes included procedural complications, 30-day readmission and accident and emergency (A&E) attendance, and length of stay. 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. Of these, 11.2% reported a procedural complication, 11.8% resulted in emergency respiratory readmission, 0.7% in respiratory A&E attendance within 30 days and 46.1% involved a post-procedure stay. Compared with published clinical trials which found lower hospitalization rates, BT patients in routine clinical practice were, on average, older, had worse baseline lung function and asthma quality of life. The authors concluded that a higher proportion of patients experienced adverse events compared with clinical trials and that the greater severity of disease among patients treated in clinical practice may explain the observed rate of post-procedural stay and readmission. The findings are limited by lack of randomization. (This review is included in the Hayes 2022 Health Technology Assessment).

Chupp et al. (2017) reported data on a total of 284 study subjects enrolled in two different studies that had completed 3-year follow-up visits. By their 3-year follow-up visits after BT treatment, the subjects were able to significantly reduce their mean inhaled corticosteroid (ICS) daily dose. The percentage of subjects who were taking daily oral corticosteroids (OCSs) to improve asthma control was reduced from 18.9% at baseline to 10.2%. At year 3 after BT, the percentage of subjects with severe exacerbations, emergency department visits and hospitalizations significantly decreased by 45%, 55% and 40%, respectively. Pre-bronchodilator FEV1 remained unchanged from baseline throughout the 3-year follow-up period. Post-bronchodilator FEV1 remained higher than pre-bronchodilator values at all times. The authors reported that BT is a safe procedure, and that it significantly reduces steroid exacerbations, emergency department visits and hospitalizations in severe asthmatic subjects compared with the 12 months before BT treatment. The study is limited by lack of comparison with a contemporary control group undergoing a different therapy.

Zhou et al. (2016) performed a systematic literature review of peer-reviewed studies (n = 6) focusing on BT intervention in asthma control published between January 2000 and June 2014 to evaluate the long-term efficacy and safety of BT in the treatment of patients with moderate-to-severe persistent asthma. Two hundred and forty-nine subjects between the ages of18 and 65 years , diagnosed with moderate-to-severe persistent asthma, requiring daily therapy with inhaled corticosteroid (ICS) and who received BT procedures at least once using the Alair system were included in the studies. Outcomes assessed after BT included spirometric data, adverse respiratory events, emergency room (ER) visits and hospitalization for respiratory illness at a one year and five-year follow-up. No evidence of significant decline was found in pre-bronchodilator forced expiratory volume (FEV1), or in post-bronchodilator FEV1 between one year and five years. The most common side effects were airway irritation, including worsening asthma symptoms (wheezing, chest discomfort, cough, and chest pain), and upper respiratory tract infections. The frequency of respiratory adverse events was reduced significantly during the follow-up. The number of ER visits for adverse respiratory events remained unchanged after BT treatment. There was no statistically significant increase in the incidence of hospitalization for respiratory adverse events. The authors concluded that BT shows reasonable long-term safety and efficacy for moderate-to-severe asthmatic patients. A large-scale clinical study should be performed for confirming 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 5-year follow-up. The authors state that findings from current studies are based merely on clinical manifestations and outcomes and that histological assessment after BT treatment could provide more evidence to support the findings. (This review is included in the Hayes 2022 Health Technology Assessment and ECRI 2020 Clinical Evidence Assessment).

A Cochrane systematic review by Torrego et al. (2014) concluded, based on the review of three trials (429 participants) that BT for patients with moderate to severe asthma provides a modest clinical benefit in quality of life and lower rates of asthma exacerbation, but no significant difference in asthma control scores. The quality-of-life 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 adverse events 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 2022 Health Technology Assessment and ECRI 2020 Clinical Evidence Assessment).

A meta-analysis by Wu et al. (2011) assessed the safety and efficacy of BT in patients with moderate to severe asthma. Compared with standard medications and sham treatment (combined), BT caused more adverse respiratory events and hospitalizations, but most events resolved within a week. While the two randomized controlled trials that did not include a sham procedure appeared to show some benefits on quality of life and peak flow, these findings were not significant for the sham-controlled trial. The authors concluded that additional long-term randomized controlled trials are needed to confirm whether BT provides benefit to patients with moderate to severe persistent asthma. (This review is included in the ECRI 2020 Clinical Evidence Assessment).

Clinical Practice Guidelines

American College of Chest Physicians (CHEST)

In a 2014 position statement for coverage and payment for BT, CHEST states BT offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment.

British Thoracic Society (BTS)

A BTS July 2019 guideline on the management of asthma states the following:

- Bronchial thermoplasty may be considered for the treatment of adult patients with severe asthma who have poorly controlled asthma despite optimal therapy.
- 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 center 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 recommended into factors that identify patients who will or will not benefit from bronchial thermoplasty treatment (Grade B rating).

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

In a joint guideline on severe asthma, the ERS and the ATS recommend 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 (strong recommendation, very low-quality evidence). The guidelines also include data regarding the increased risk of adverse events. Three studies on bronchial thermoplasty demonstrated increased risk of hospitalization (relative risk [RR]: 2.3, 95% confidence interval [CI]: 1.3–3.9). All studies reported adverse effects related to respiration only. Bronchial thermoplasty increased the risk of respiratory adverse effects in the initial treatment phase (relative risk [RR]: 1.13, 95% CI: 0.99–1.28 [number of patients with at least 1 adverse event]; rate ratio: 3.3, 95% CI: 2.4–4.5 [number of adverse events]), irrespective of their severity.

According to guideline authors, both the potential benefits and harms may be considerable and the long-term consequences are unknown regarding this new approach to asthma therapy with an invasive physical intervention. Well-designed clinical studies are needed to define its effects on relevant objective health outcomes, such as exacerbation rates, and lung function, assessed over the long term. Studies are also needed to better understand the phenotypes of responding patients, the effect of the technology in patients with severe obstructive asthma (FEV_1 < 60% of predicted value), and in patients being treated with systemic corticosteroids. Further research is likely to have an important impact on this recommendation (Chung et al., 2014).

Global Initiative for Asthma (GINA)

In 2023 GINA guidelines lists the following recommendations for bronchial thermoplasty:

- Adult patients who are managing severe asthma that remains uncontrolled despite optimal asthma therapy and after a referral to severe asthma specialty center, bronchial thermoplasty may be considered as a treatment option for highly selected adults with severe asthma. But caution should be in used in patient selection as long-term effects and lung function are not known.
- Evidence is limited, smaller study groups and in selected patients their asthma treatment was not optimized prior to a bronchial thermoplasty (Evidence level B – limited body of data).

Large cohort studies are needed, longer-term follow-up and lung function comparing effectiveness and safety in both actively treated and sham-treated patients to identify its efficacy and long-term safety in broader severe asthma populations.

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

An Expert Panel Working group of NAEPPCC coordinated with NHLBI adopted these 2020 guidelines for bronchial thermoplasty (BT). Patients that are 18 years and older with uncontrolled, moderate-to-severe, persistent asthma should not undergo BT due to small patient benefit with moderate risk and long-term outcomes that are uncertain. This rationale is based on three randomized control studies with a total of 432 patients undergoing either treatment with high-dose fluticasone, long-acting beta agonists (LABA), with or without daily oral corticosteroids and omalizumab. The intervention group underwent either a sham bronchoscopy or BT. Both interventions patients received medicinal treatment in some combination as well. The expert panel concluded there is low certainty of evidence, and if patients do receive BT they should be enrolled in registries, ongoing clinical trials, or studies that can track long-term safety and effectiveness.

National Institute for Health and Care Excellence (NICE)

A 2018 NICE interventional procedures guidance on bronchial thermoplasty for severe asthma included evidence from 2 systematic reviews with meta-analysis, 1 randomized controlled trial, 3 case series (2 of which were extensions of randomized trials; evidence from 1 was extracted from 2 published sources), 1 non-randomized comparative study, 1 registry and 5 case reports. The committee found that there is uncertainty about which patients may benefit from the procedure and that BT should only be used for severe asthma that is not controlled despite optimal drug treatment. Further research should report details of patient selection and long-term safety and efficacy outcomes.

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.

The Alair® Bronchial Thermoplasty System (Asthmatx, Inc.) received premarket approval on April 27, 2010 (P080032). Alair is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta agonists. Refer to the following website for more information (use product code OOY): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed May 30, 2023)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information. • Archived previous policy version CS014KY.03

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.