

Bronchial Thermoplasty (for Tennessee Only)

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[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Applicable Codes	1
Description of Services	1
Clinical Evidence	2
U.S. Food and Drug Administration	7
Centers for Medicare and Medicaid Services	7
References	7
Policy History/Revision Information	8
Instructions for Use	9

Commercial Policy
• Bronchial Thermoplasty

Application

This Medical Policy applies to Medicaid only plans in the state of Tennessee.

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 federal, state or contractual requirements 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 Coverage Determination 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

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Description of Services

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation(Reddel 2015). 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 or long-acting beta2-agonists, help reduce airway inflammation and prevent asthma symptoms. Quick-relief medications, such as short-acting beta2-agonists, relieve asthma symptoms that may cause flare of symptoms.

Bronchial thermoplasty (BT) is a procedure for treating severe persistent asthma in patients whose asthma is not well controlled with conventional drug therapy. The procedure uses thermal energy (radiofrequency) to ablate and reduce the volume of smooth muscle tissue, inhibit airway constriction and theoretically reduce the severity and frequency of asthma symptoms. BT is performed using a standard flexible bronchoscope, which is introduced through the nose or mouth and into the lungs. The tip of a small diameter catheter expands to reach the walls of targeted airways. Controlled thermal energy is then delivered to the airway walls to reduce excess smooth muscle tissue. This is a minimally invasive procedure that usually requires moderate sedation or light anesthesia and is performed over three outpatient visits, each treating a different area of the lung.

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 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.

An ECRI clinical evidence assessment report on the Alair™ Bronchial Thermoplasty System focused on how well Alair works for treating severe asthma in 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 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)

A Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma (PAS2) study was designed to demonstrate the short- and long-term treatment effectiveness and safety profile of the Alair® system in the intended use population (patients 18 years and older with severe persistent asthma). This is a prospective, multicenter, open-label, single arm study with a start date of April 2011 and an estimated completion date of January 2020. The primary endpoint will be the proportion of subjects experiencing severe exacerbations during the subsequent 12-month (for years 2, 3, 4, and 5) compared to the first 12-month after the Alair® treatment. To date, the results of this clinical trial have not yet been published. ClinicalTrials.gov Identifier: NCT01350336.

Seeley et al. (2019) performed a prospective study of the impact of BT in 25 patients with severe persistent asthma. The aim of the study was to determine the impact of BT on asthma QOL measures (mini-AQLQ) and asthma controller medication use during the year following treatment with BT. Results showed 88% of the patients showed a clinically significant improvement in mini-AQLQ at 1 year. Patients treated with BT showed a reduction in the use of montelukast and omalizumab 1 year after BT.

A prospective cohort of 32 consecutive patients with severe asthma who received BT was performed by Langton et al. (2018a). The individuals were evaluated at baseline, 6 weeks and 6 months post completion of all procedures. At each evaluation, medication usage, symptom scores (Asthma Control Questionnaire, ACQ-5) and exacerbation history were obtained, and lung function was evaluated by spirometry gas diffusion (KCO) and static lung volumes by body plethysmography. ACQ-5 improved from baseline to 6 months. Daily salbutamol usage improved. The mean baseline FEV1 was $57.8 \pm 18.9\%$ predicted, but no changes in any spirometric parameter were observed after BT. KCO was also unaltered by BT. A significant reduction in gas trapping was observed with residual volume (RV) falling. Improvements in total lung capacity and functional residual capacity were also observed. These changes were evident at the 6-week time period and maintained at 6 months. The authors concluded that bronchial thermoplasty improves gas trapping and this effect is greatest in the most severely obstructed patients. The substantive clinical response to BT without any accompanying change in spirometry suggests that BT affects small peripheral airway function. Support for this concept is seen by the reduction in residual volume after treatment, accompanied by a reduction in RV/TLC ratio in more obstructed patients. This was uncontrolled, observational data presented

in this study. It is anticipated that further studies using more sensitive measures of small airways dysfunction, such as impedance oscillometry and multiple breath nitrogen washout, will be necessary to confirm the observations made.

Langton et al. (2018b) conducted a single center, observational study of 20 consecutive patients with very severe asthma undergoing BT. BT was performed in three treatments, each 4 weeks apart. The primary outcome parameter in this study was change in the post bronchodilator FEV1. The aim of the study was to quantify the major side effect of BT, aggravation of asthma. The mean baseline pre-bronchodilator FEV1 was $52.3 \pm 15.2\%$ predicted, with a mean change in FEV1 post-bronchodilator of $+19.5 \pm 15.3\%$. The pre-bronchodilator forced expiratory ratio was $51.4 \pm 12.6\%$. The mean ACQ-5 was 3.3 ± 1.1 . Twenty-four hours after BT, the mean deterioration in post-bronchodilator FEV1 was 166 ± 237 ml or $9.1 \pm 15.2\%$ of baseline. This deterioration was significantly greater after upper lobe procedures, where a mean fall in FEV1 of $17.1 \pm 12.6\%$ was observed. The change in FEV1 post procedure was significantly correlated with the number of radiofrequency activations applied. When the lower lobes were treated, the post-bronchodilator FEV1 had returned to baseline values by day 3, but patients took 7 days to recover after upper lobe treatments. The authors concluded that the deterioration in lung function after BT is transient and well tolerated, greatest after upper lobe treatment, and is significantly related to the number of radiofrequency activations applied. Limitations include small sample size and short duration of follow-up.

A 2018 National Institute for Health and Care Excellence (NICE) interventional procedures guidance on bronchial thermoplasty for severe asthma document included evidence from 2 systematic reviews with meta-analysis, 1 randomised controlled trial, 3 case series (2 of which were extensions of randomised trials; evidence from 1 was extracted from 2 published sources), 1 non-randomised 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.

Niven et al. (2018) conducted an indirect treatment comparison (ITC) to appraise comparative effectiveness of BT and omalizumab (OM). A systematic literature review identified relevant randomized controlled trials ($n=7$). The ITC comprised a sham-controlled trial of BT (AIR2) and two placebo-controlled trials of OM (INNOVATE; EXTRA). Comparing the BT post-treatment period to ongoing treatment with OM, showed no significant differences in the rate ratios (RRs) for severe exacerbations or hospitalizations; emergency department visits were significantly reduced by 75% with BT; the proportions of patients with meaningful clinical response on the asthma quality-of-life questionnaire were comparable. The authors concluded that the ITC should be interpreted cautiously due to the differences between patient populations in the included trials, however BT compares well with pharmacotherapy for asthma. Differences across the trials in terms of the duration of follow-up are acknowledged. It is acknowledged that the patients in the BT trials were less severely affected by their asthma than the patients in the OM trial and may place potential limitations on the interpretation of the results of the analysis.

Chupp et al. (2017) compared a total of 284 study subjects enrolled in a PAS2 study and 190 have completed 3 year follow-up visits. By their 3-year follow-up visits after BT treatment, the PAS2 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 bronchial thermoplasty, the percentage of PAS2 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 (Chupp et al [2017]) report that the PAS2 study results show 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 authors concluded that PAS2 data suggests that the treatment effect of BT is both consistent and durable even in subjects with poorly controlled asthma who may have associated comorbidities and more severe asthma. There was a continual improvement in asthma control during the first 3 years after BTI thermoplasty treatment. They acknowledged that the study entry criteria for PAS2 have some restrictions and the most severe asthma subjects seen in clinical practice were not included in the PAS2 study.

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 in any population. 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.

Krmisky et al. (2017) reviewed three randomized controlled trials evaluating efficacy and safety of BT in patients with mild to moderate asthma. They noted that the trials have demonstrated an improvement in quality of life and a reduction in overall health care usage with this treatment. The largest advantage is demonstrated in reduction of exacerbations and hospitalizations following treatment. The contraindications to having BT performed include age younger than 18 years, presence of implantable devices such as internal defibrillator or pacemaker, sensitivity to medications administered during the procedure such as lidocaine and benzodiazepines and previous BT therapy. The authors concluded that BT therapy is a good option as add on therapy in carefully selected patients. The exact asthma phenotype that would benefit from this treatment is yet unclear. More research needs to be done to determine the ideal asthma patient that would benefit from BT, with particular attention on the effect of intervention in patients with most severe disease.

Pretolani et al. (2017) examined the effect of BT on bronchial structures and explored the association with clinical outcome in patients with severe refractory asthma. Bronchial biopsy specimens (n=300) were collected from 15 patients with severe uncontrolled asthma before and 3 months after BT. Immunostained sections were assessed for airway smooth muscle (ASM) area, subepithelial basement membrane thickness, nerve fibers, and epithelial neuroendocrine cells. Histopathologic findings were correlated with clinical parameters and were associated based on Asthma Control Test scores, numbers of exacerbations, and visits to the emergency department 3 and 12 months after BT. At 3 months, the clinical benefit noted was a reduction in ASM area (median values before and after BT, respectively: (19.7% and 5.3%), subepithelial basement membrane thickening (4.4 μm and 3.9 μm), submucosal nerves (1.0 ‰ immunoreactivity and 0.3 ‰ immunoreactivity), ASM-associated nerves (452.6 immunoreactive pixels per mm and 62.7 immunoreactive pixels per mm) and epithelial neuroendocrine cells (4.9/mm and 0.0/mm). Six of the 15 BT-treated patients with severe asthma still experienced uncontrolled asthma at 3 months and 4 at 12 months. The authors concluded that BT significantly improved asthma control and quality of life at both 3 and 12 months and decreased the numbers of severe exacerbations and the dose of oral corticosteroids. They further state that BT is a treatment option in patients with severe therapy-refractory asthma that downregulates selectively structural abnormalities involved in airway narrowing and bronchial reactivity, particularly ASM, neuroendocrine epithelial cells, and bronchial nerve endings. The small study population limits the validity of the conclusion of this study.

Patients were recruited in the setting of a prospective clinical trial aimed at evaluating the effect of bronchial therapy (BT) in patients with severe therapy-uncontrolled asthma (Debray et al., 2017). Unenhanced chest CT was performed the day after each BT session in 13 patients with severe asthma, leading to the examination of 38 treated lobes. A total of 15 BT-treated lobes were evaluated in 11 patients at 1 month. Follow-up CT examinations were performed at 1 week in the first two patients to assess the evolution of opacities. No symptoms suggestive of pulmonary infection were noted following BT in any patient. Peribronchial consolidations were present on the day after BT in all treated lobes with three lower lobes showing complete collapse. Mild involvement of an adjacent untreated lobe was observed in 12 out of 38 (32%) cases. Opacities had decreased in 5 out of 15 (33%) and disappeared in 10 out of 15 (67%) at 1 month. Mild focal bronchial dilatations were noted a few months later in three treated lobes. The authors concluded that the mechanism and clinical significance of such dilatations deserve further evaluation. The limitations of the study include 1) the low number of patients with severe asthma examined, 2) the lack of histologic correlation to explain the nature of pulmonary opacities, and 3) the short duration of the follow-up.

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 bronchial thermoplasty. The 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. Study of long-term safety and efficacy requires continuing data collection.

Global Initiative for Asthma (GINA) guidelines on managing asthma state that bronchial thermoplasty may be considered for highly-selected adult patients with uncontrolled asthma despite use of recommended therapeutic regimens and referral to an asthma specialty center. Evidence is limited and in selected patients (Evidence level B – limited body of data). More studies are needed to identify its efficacy and long-term safety in broader severe asthma populations (GINA, 2016. Updated 2018).

A 2016 Hayes Medical Technology Assessment Directory Report of bronchial thermoplasty reviewed seven studies, including 1 good-quality randomized controlled trial (RCT), 2 fair-quality RCTs, 1 very-poor-quality retrospective cohort study, and 3 very-poor-quality case series. The report concluded that a small, low-quality body of evidence suggests that during the first year following treatment, BT may improve quality of life (QOL) outcomes. Some evidence also suggests symptom relief, reductions in emergency department visits, and reduced medication use; however, the results were inconsistent across studies. Hayes noted that BT did not reduce the rate of hospitalizations following treatment, and increased hospitalization during the treatment period. The report notes current evidence is insufficient to establish the long-term safety and efficacy of bronchial thermoplasty.

In the Hayes 2019 annual review, twelve abstracts were retrieved with low-quality of evidence which suggested some positive but inconsistent results regarding short-term benefits of BT. There was insufficient evidence concerning the long-term safety and efficacy of BT.

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 of 18 and 65 years, diagnosed with moderate-to-severe persistent asthma, requiring daily therapy with inhaled corticosteroid (ICS) and whom 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 5 year. 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.

An assessment by the BlueCross BlueShield Association Technology Evaluation Center (March 2015) concluded that there is a sizeable population with severe persistent asthma that could be considered for bronchial thermoplasty. Evidence from the three trials compared outcomes following BT with controls. Results from the single sham-controlled trial are not sufficient to establish comparative benefit. There is little published evidence obtained outside the investigational setting concerning potential harms and benefit. They concluded that BT for treatment of inadequately controlled severe asthma does not meet the Blue Cross Blue Shield Association Technology Evaluation Center (TEC) criteria.

A Cochrane review by Torrego et al. (2014) concluded 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 are 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. For clinical practice, it would be advisable to collect data from patients systematically in independent clinical registries. Further research should

provide better understanding of the mechanisms of action of bronchial thermoplasty, as well as its effect in different asthma phenotypes or in patients with worse lung function.

Wechsler et al. (2013) followed 162 (85.3%) BT-treated patients from the AIR2 trial for 5 years to assess the long-term safety of BT and the durability of its treatment effect. Outcomes assessed after BT included severe exacerbations, adverse events, health care use, spirometric data and high-resolution computed tomographic scans. Severe exacerbations and emergency department (ED) visits in years 1 to 5 remained low and were less than those observed in the 12 months before treatment (average 5-year reduction in proportions: 44% for exacerbations and 78% for ED visits). Respiratory adverse events and respiratory-related hospitalizations remained unchanged in years 2 through 5 compared with the first year after therapy. Prebronchodilator FEV1 values remained stable between years 1 and 5 after therapy, 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 these results demonstrate the 5-year durability of BT benefits with regard to both asthma control and safety. This observational study is limited by lack of a control group in the longer follow-up period. As with the original study, a potential for bias exists due to manufacturer sponsorship.

Patients enrolled in the Asthma Intervention Research (AIR) Trial were invited to participate in a 4 year safety study. Adverse events (AEs) and spirometry data were used to assess long-term safety out to 5 years post-bronchial thermoplasty (BT). 45 of 52 treated and 24 of 49 control group subjects participated in long-term follow-up of 5 years and 3 years respectively. The rate of respiratory adverse events (AEs/subject) was stable in years 2 to 5 following BT. There was no increase in hospitalizations or emergency room visits for respiratory symptoms in years 2, 3, 4 and 5 compared to year 1. The FVC and FEV1 values showed no deterioration over the 5 year period in the BT group. Similar results were obtained for the control group. The absence of clinical complications and the maintenance of stable lung function over a 5-year period post-BT in this group of patients with moderate to severe asthma support the long-term safety of the procedure out to 5 years. This study is limited by the nonblinded study design and the potential for bias due to manufacturer sponsorship (Thomson et al., 2011).

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, BT caused more adverse respiratory events and hospitalizations, but most events resolved within a week. 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.

Professional Societies

American College of Allergy, Asthma and Immunology (ACAAI)

In a 2015 statement, the ACAAI states that “Bronchial thermoplasty is a well-studied treatment for patients with very severe asthma who continue to be symptomatic despite maximal medical treatment including steroids, long-acting beta agonists (LABAs), long-acting muscarinic agents (LAMAs), leukotriene antagonists and biologics. The scientific literature supports bronchial thermoplasty as a therapeutic consideration for some carefully chosen patients with severe asthma. 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.”

American College of Chest Physicians (CHEST)

In a 2014 document titled ‘Coverage and Payment for Bronchial Thermoplasty for Severe Persistent Asthma’, CHEST notes bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental.

British Thoracic Society (BTS)

A BTS October 2016 guideline on the management of asthma states that bronchial thermoplasty may be considered for the treatment of adult patients who have poorly controlled asthma despite optimal therapy. Assessment and treatment for bronchial thermoplasty should be undertaken in centers that have expertise in the assessment of difficult to control asthma and in fiberoptic bronchoscopic procedures. The balance of risks and benefits of bronchial thermoplasty treatment should be discussed with patients being considered for the procedure. Longer term follow up of treated patients is recommended. Further research is recommended into factors that identify patients who will or will not benefit from bronchial thermoplasty treatment (Grade A – highest 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 (FEV1 <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).

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. See the following website for more information (use product code OOY): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. (Accessed May 15, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for bronchial thermoplasty. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed June 1, 2020)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2021	<p>Template Update</p> <ul style="list-style-type: none"> Reformatted policy; transferred content to new template Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in <i>Instructions for Use</i>
10/01/2020	<p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information Archived previous policy version CS014TN.I

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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