

BRONCHIAL THERMOPLASTY

Policy Number: RESPIRATORY 009.14 T2

Effective Date: December 1, 2018

[Instructions for Use](#) ⓘ

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Related Policies

None

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

NON-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 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 (Redden 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 over three outpatient visits, during which a different area of the lung is treated.

CLINICAL EVIDENCE

Niven et al. (2018) conducted an indirect treatment comparison (ITC) to appraise comparative effectiveness of bronchial thermoplasty (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.

A systematic review to assess the effectiveness and safety of bronchial thermoplasty (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.

Pretolani et al. (2017) examined the effect of bronchial thermoplasty (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.

Zhou et al. (2016) performed a systematic literature review of peer-reviewed studies (n=6) focusing on bronchial thermoplasty (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 bronchial thermoplasty 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.

The 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. A total of 284 study subjects were enrolled in the PAS2 study and 190 have completed 3 year follow-up visits. By their 3-year follow-up visits after bronchial thermoplasty 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 bronchial thermoplasty 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 bronchial thermoplasty treatment. The authors concluded that PAS2 data suggests that the treatment effect of bronchial thermoplasty 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 bronchial 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.

Langton et al. (2018) conducted a single center, observational study of 20 consecutive patients with very severe asthma undergoing bronchial thermoplasty (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 mls 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.

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, bronchial thermoplasty 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.

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, bronchial thermoplasty 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 bronchial thermoplasty 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 2018 annual review, six abstracts were retrieved with low-quality of evidence which suggested some positive but inconsistent results regarding short-term benefits of bronchial thermoplasty. There was insufficient evidence concerning the long-term safety and efficacy of bronchial thermoplasty.

A 2016 National Institute for Health and Care Excellence (NICE) guidance report on Alair bronchial thermoplasty system for adults with severe difficult to control asthma found that evidence from 3 systematic reviews of mixed quality suggests that use of the Alair system is associated with some patient benefits (such as improved quality of life, and morning peak expiratory flow), but not all benefits were considered to be clinically significant. There is mixed evidence in relation to other outcomes (including asthma exacerbations, hospitalizations and emergency department visits).

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.

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)

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.

A National Institute for Health and Care Excellence (NICE) guidance document states that the evidence on the efficacy of bronchial thermoplasty for severe asthma shows some improvement in symptoms and quality of life, and reduced exacerbations and admission to hospital. Evidence on safety is adequate in the short and medium term. More

evidence is required on the safety of the procedure in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. (NICE, 2012)

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 bronchial thermoplasty 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 bronchial thermoplasty for treatment of inadequately controlled severe asthma does not meet the Blue Cross Blue Shield Association Technology Evaluation Center (TEC) criteria.

Professional Societies

American College of Allergy, Asthma and Immunology (ACAAI)

In a 2015 statement on bronchial thermoplasty 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".

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 on 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 are used. Further research is likely to have an important impact on this recommendation. (Chung et al., 2014)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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 OOO): <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpMA/pma.cfm>. (Accessed April 20, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0542N]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	<ul style="list-style-type: none">Simplified non-coverage rationale (no change to guidelines)Archived previous policy version RESPIRATORY 009.13 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.