Cigna Medical Coverage Policy

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Subject **Bronchial Thermoplasty**

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Coverage Policy

Cigna does not cover bronchial thermoplasty for any indication because it is considered experimental, investigational or unproven.

General Background

Asthma is a chronic inflammatory disorder of the airways characterized by recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. Clinical studies have shown that asthma can be effectively controlled by intervening to suppress and reverse inflammation as well as treating the bronchoconstriction and related symptoms (Global Initiative for Asthma [GINA], 2014). The goal of the treatment of asthma is to achieve and maintain clinical control by eliminating symptoms during both the day and night, to normalize measures of lung function, and to reduce the risk of future exacerbations (California Technology Assessment Forum [CTAF], 2011; GINA, 2014). Depending on level of control, standard treatment options may include stimulus avoidance and an as-needed reliever medication (e.g., rapid-acting short- or long acting inhaled $beta_2$ [B_2] agonist), reliever treatment with regular controller treatment (e.g., inhaled glucocorticosteroid, leukotriene modifier, theophylline, cromones), oral glucocorticosteroids, or a combination of these and other medications (GINA, 2014).

While the patient continues to take standard asthma medications as scheduled, bronchial thermoplasty has been proposed as a potential treatment option for adults with severe, persistent asthma that is refractory to other therapies. Bronchial thermoplasty (BT) is a minimally invasive technique intended to decrease the number of severe asthma attacks on a long-term basis by reducing, debulking, or partially eliminating excess smooth muscle tissue in the patient's distal airways (ECRI, 2013).

The Alair® System is currently the only bronchial thermoplasty device approved by the U.S. Food and Drug Administration (FDA). According to the manufacturer, the Alair® Bronchial Thermoplasty System (Asthmatx, Boston Scientific Corporation, Natick, MA) consists of a catheter, radiofrequency controller, patient return electrode, foot switch and catheter electrical cable. The Alair® Catheter is a sterile, single-use, disposable device and has an electrode basket at the distal tip of the catheter. The electrode basket has four stainless steel wire legs. Each leg is insulated with polyester heat shrink, leaving a 5 mm long exposed area at the center of the leg that is the active electrode, or energy delivering region. Visual contrast between the insulation and the exposed active electrode provides visual feedback to the user during bronchoscopy. The Alair® Radiofrequency (RF) Controller is reusable and non-sterile. It delivers low-power (18 watts maximum), temperature-controlled RF energy to the airway at a treatment setting of 65°C for a duration of 10 seconds. The controller automatically limits the energy delivered in any activation to a maximum of 120 joules.

The Alair® System is designed for treatment of the airways distal to the main stem bronchi, down to airways of ≥3mm in diameter (Boston Scientific, 2014). BT using this system comprises a series of procedures, with one bronchial area being treated per session. To treat all accessible airways in both lungs, three sessions are required at a minimum of three-week intervals. Treatment takes about 45 minutes for lower lobes and 60 minutes for upper lobes (Boston Scientific, 2014). With the patient undergoing moderate sedation or general anesthesia a flexible bronchoscope is placed into the bronchial tree via the oral or nasal route. The Alair Catheter is introduced into the airways through the working channel of the bronchoscope. The bronchoscope is navigated to the first target site, typically the most distal airway in the targeted lobe. The electrode array at the tip of the catheter is expanded to gain contact with the airway wall and radiofrequency energy is delivered to the tissue. Energy delivery during activation is limited to a temperature of 65°C (149°F). During the first treatment, the physician ablates the rings of airway smooth muscle in the bronchioles of the lower lobe of the right lung. At least three weeks later, the left lung's lower lobe is treated. Finally, at least three weeks later, both upper lobes are treated (Boston Scientific, 2014).

Literature Review

Bronchial thermoplasty (BT) is a novel treatment for adult patients with severe asthma who remain symptomatic despite adherence to the standards of medical care (Wahibi, 2011). According to Wahibi (2011), "Proper patient selection and optimal pre- and post-procedural management are essential for a successful outcome. Further studies are needed to determine the durability of clinical effects, assess long-term adverse events, and further understand the mechanism of BT on asthma pathobiology."

Several randomized clinical trials (RCT) have published two-year outcome data suggesting improved Asthma Quality of Life Questionnaire (AQLQ) scores and some improvement in the rate of severe exacerbations, emergency department (ED) visits and days lost from school/work in a small number of patients. Three follow-up studies have also reported five-year outcomes in subsets of the patients who underwent treatment with BT.

According to Wahibi (2011) "The generalizability of these findings to all patients with severe asthma is not clear, given the exclusion of patients with severe asthma who exacerbate frequently, require multiple bursts of oral corticosteroids, and demonstrate low lung function. This necessitates additional investigation to identify disease and patient characteristics that would enable accurate phenotyping of positive responders to avoid unnecessary procedures and risks. There is a pressing need to understand the underlying mechanism of BT and how its delivered heat is translated into clinical benefit. Ongoing and future studies should attempt to obtain endobronchial biopsies from treated areas with close examination of alterations in anatomical structures and inflammatory markers. Prior histological data of BT effects on the airways had come from animal models or subjects who did not carry the diagnosis of asthma. The ability to deliver biological agents, systemically or via inhalation, which can disrupt the function of the airway smooth muscle would be an attractive strategy that reaches proximal and distal airways and is delivered in a less invasive fashion."

Castro et al. reported data from a multicenter blinded RCT (n=288), the Asthma Intervention Trial 2 ([AIR2], 2010) with BT (n=190) compared with a sham control group (n=98); each participant undergoing at least one bronchoscopy. The bronchoscopy was not blinded to participants; however, BT use was blinded. In the BT group, a greater proportion of patients correctly guessed their treatment assignment after the first bronchoscopy (BT, p=0.011; sham, p=0.342). Although the data suggest patients receiving BT experienced some improvement in quality of life and reduction in the rate of severe exacerbations, ED visits, and days lost from school or work in the post-treatment period (i.e., 6-52 weeks after bronchial thermoplasty) compared to baseline, individuals treated with sham also achieved improvement from baseline.

The primary endpoint of improvement on the Asthma Quality of Life Questionnaire (AQLQ) score and secondary endpoints (e.g., Asthma Control Questionnaire [ACQ] scores, percent of symptom-free days, rescue medication use, percentage and number of severe exacerbations, respiratory-related unscheduled physician office visits, emergency department visits, hospitalizations and days missed from work/school) were analyzed using the Bayesian method. The pre-specified posterior probability of superiority (PPS) that is significant for the primary outcome is 96.4% and 95% for secondary outcomes. Outcomes were reported from first day of bronchoscopy through 12-month follow-up, the treatment period: (bronchoscopy to six-weeks), and post-treatment (six weeks-52 weeks).

The BT group showed greater net benefit in AQLQ scores from baseline compared with the sham group (PPS, 100.0). Changes in individual domains of AQLQ between the BT and sham groups were not significant except for the emotional function domain. Over the entire study period (from the day of first bronchoscopy to the 12-month follow-up), sham was superior over BT for the number of severe exacerbations, number of ED visits for respiratory symptoms per subject, and the number of respiratory-related hospitalizations per subject. Using the intent-to treat-population, secondary endpoint measures of morning PEF, symptom-free days, symptom score, ACQ, and rescue medication use showed an improvement over baseline in the BT and the sham groups, differences between the groups were not statistically significant (PPS, <95.0%). In the treatment period there were more adverse events (AE) in the BT group than the sham group (85% versus 76%, PPS not reported), in the post-treatment period, there were fewer AEs in the BT group compared to sham (70% versus 80%). During the post-treatment period BT was superior over sham for risk reduction for reported worsening of symptoms (PPS, 99.7%) and ED visits (PPS, 99.9%). Variables which limit the ability to assess whether there is a net improvement in health outcomes include the fact that the study did not meet its primary endpoint and the superiority of sham over BT for several secondary endpoints.

Regarding the study, Bel (2010) noted, “Bronchial thermoplasty appears to have a benefit on the quality of life and severe exacerbations. Importantly, severe asthma has many phenotypes, and at present we have no clue which phenotype will benefit the most. It is inevitable that phenotypic targeting will be essential for this invasive procedure. Moreover, we need to know how durable the benefit will be to ensure that the benefits outweigh the risks and burden of the procedure. Therefore, long-term clinical and morphological research in various severe-asthma phenotypes is still needed to obtain the required information for clinical decisions".

In a five-year follow-up to the Asthma Intervention Trial 2 ([AIR2], Weschler et al. (2013) assessed the effectiveness and safety of BT in 162 of 190 asthmatic patients who had received BT. Results for year one were calculated beginning from six weeks post the last BT procedure. Outcomes assessed after BT included severe exacerbations, adverse events, health care use, spirometric data, and high-resolution computed tomographic scans. The proportion of subjects having severe exacerbations in years two-five compared with the first year after BT were not significantly different. The reduction in the proportion of subjects experiencing severe exacerbations in the year after BT compared with the 12 months before BT (51.6%) was maintained for the entire five-year follow-up period, with an average decrease of 44%. The decrease in severe exacerbation rates that was achieved in the post-treatment period after BT in year one was maintained out to five years. The authors reported that on average, both patients with FEV1 values of 60% to 70% of predicted value and those with FEV1 values >70% of predicted value had sustained improvements in exacerbations over the five-year period. There was an overall reduction of 18% in the average inhaled corticosteroid dose at five years. Of the 93 evaluable high resolution computerized tomography (HRCT) pairs at year five, 82% showed either no radiologic changes or improvement from baseline; 71% of the HRCT pairs showed no radiologic changes of clinical significance. Five-year results are promising; limitations of the study include the lack of comparison to outcomes of the sham control group participants of the original AIR2 trial.

In another randomized controlled trial (RCT), Pavord et al. (Research in Severe Asthma [RISA], 2007) examined the safety and effectiveness of BT in patients with symptomatic, severe asthma. Adults who were symptomatic despite treatment were randomized to BT (n=15) or to a control group (n=17). Those treated with BT received three procedures, three weeks apart. All subjects maintained baseline asthma medications. After treatment, subjects entered a 16-week steroid stable phase (weeks 6 to 22), a 14-week steroid wean phase (weeks 22 to 36), and a 16-week reduced steroid phase (weeks 36 to 52). Investigators were not blinded to treatment. The primary study endpoint was to determine the safety of BT in subjects with symptomatic, severe asthma. Secondary endpoints were the evaluation of the effect of BT on asthma symptoms and daily medication

requirements. Improvements in primary and secondary endpoints were noted in both treatment groups compared to baseline.

The safety of BT was assessed by monitoring adverse events and pulmonary function. Subjects completed diaries to report adverse events. Adverse events were designated as respiratory- or non–respiratory-related. In the treatment period there was an increase in respiratory adverse events and hospitalizations in the group undergoing BT compared with control. Two subjects in the BT group had segmental collapse involving the most recently treated lobe; one required mucus plug aspiration. In the post treatment period the rate of hospitalizations was similar in both groups (p=.32).

At 22 weeks, patients who received BT had significant improvements versus those of control subjects in rescue medication use ($p < 0.05$), and pre-bronchodilator forced expiratory volume in 1 second (FEV1) % predicted ($p = 0.04$). Short-term improvements up to 52 weeks were seen during the steroid stable phase. The authors note that longer and larger studies of subjects with different asthma severity are required to determine whether or not there are delayed adverse effects. Although results are promising, small participant numbers and lack of blinding prohibit the ability to apply study results to use of BT in clinical practice.

In a five-year follow-up study of the RISA trial, Pavord et al. (2013) reported results of 15 patients who received BT in the previous trial. Fourteen patients completed follow-up evaluations at three years, 12 at four years, and 12 at five years. Patients were evaluated annually at the end of 12 months following BT and years two-five after their last treatment bronchoscopy. Subjects were evaluated for prebronchodilator and postbronchodilator spirometry, chest radiography, information on any adverse events (AEs), emergency department (ED) visits, and hospitalizations for respiratory symptoms, oral corticosteroid (OCS) pulses for worsening asthma symptoms, and any changes in maintenance asthma medications. Radiography was reviewed by unmasked radiologists and observations reported. Patients were questioned regarding satisfaction with the procedure and if they would recommend it to a friend or family member. The rate of respiratory AEs was unchanged in years two to five. The overall rate of respiratory hospitalizations during the five-year follow-up after BT of 0.23 per patient per year compared to a pre-procedure rate of 0.71 hospitalizations per patient per year reflected a 68% reduction. No significant changes were found in overall inhaled maintenance asthma medication use. There were no significant changes in radiographic findings over time. Mean prebronchodilator and postbronchodilator FEV1 values were also unchanged over time. Eleven patients, who completed the five-year follow-up, reported satisfaction with the procedure. Data suggest promising five-year outcomes for the twelve patients completing this study; however, small participant numbers limit the ability to translate results to a larger population.

Cox et al. reported outcomes of an RCT (Asthma Intervention Research [AIR] trial, 2007) involving 109 adults with moderate to severe persistent asthma. Both BT (n=55) and control (n=54) groups received standard of care asthma medical therapy. The primary outcome was noted to be the frequency of mild exacerbations calculated during three scheduled two-week periods of abstinence from long-acting B_2 agonists (LABA) at three, six, and 12 months. Secondary endpoints included airflow, airway responsiveness, asthma symptoms, the number of symptom-free days, use of rescue medication, and scores on the AQLQ and the Asthma Control Questionnaire (ACQ). The difference between the two groups in the change from baseline was significant at three and 12 months ($p = 0.03$ for both comparisons) but not at six months. There was an increase in adverse respiratory events immediately after the procedure for subjects undergoing bronchial thermoplasty (BT), with a return to baseline values during the post-treatment period. Overall, there were 407 adverse respiratory events in the BT group, and 106 in the control group, with a majority of events occurring within one day after the procedure. The number of hospitalizations was also greater in the BT group compared to the control group. During the post-treatment period, the proportion of subjects with adverse respiratory events and the rate of hospitalization did not differ between groups. Regarding severe exacerbations at 12 months, the difference between the two groups in the change from baseline was not significant at any time point. As compared with baseline, the average number of exacerbations during the two-week periods at three, six, and 12 months when subjects in the two groups were treated with inhaled corticosteroids alone was reduced in the BT group but was not significantly changed in the control group (p=.005). Overall, improvements in health outcomes were noted in both the BT and control groups. Further, there were increased adverse events and hospitalizations in the BT group compared with the control group. Although promising, the role of BT for the treatment of asthma is unknown at this time.

In an extension of the Asthma Intervention Research (AIR) trial, Thomson et al. (2011) reported outcomes up to five years (i.e., three years for control group [n=24], five years for BT group[n=45]) for 69 individuals with moderate to severe asthma who had completed 12 month follow-up as part of the AIR study. Endpoints were

not stated. During Years two and three, results between the BT and control groups were comparable for respiratory adverse event rates, and the number of emergency room (ER) visits during years 2 and 3 (p= 0.41 and p= 1.00, respectively). During Year 1 and Year 2, more subjects in the BT group required hospitalizations for respiratory symptoms than the control group (no p value reported). Over the course of the five year post-BT follow-up, the number of hospitalizations, and the proportion of subjects in the BT group experiencing hospitalizations for respiratory symptoms did not get worse compared to Year 1 after BT (p = 0.16). The number of ED visits for respiratory symptoms were comparable in years 2, 3, 4, and 5 compared to Year 1 (p = 0.55) for the BT group. The authors note oral corticosteroid usage for asthma symptoms was comparable between the BT and control groups during Years 1, 2 and 3 (no p value reported). The reduction in inhaled corticosteroids (ICS) was not significantly different between the BT group and the control group at years 2 and 3 (p = 0.93 and p = 0.92, respectively). This data suggest that BT did not reduce ED visits, hospitalizations, or oral corticosteroid use. Other study limitations include uncontrolled design, small patient population size, and follow-up only to three years for control group.

Cox et al. (2006) published results of an uncontrolled prospective trial involving 16 patients with stable mild to moderate asthma who underwent 49 BT procedures. Baseline and 12-week post-treatment measurements included spirometry, methacholine challenge, daily diary recordings of peak flow, symptoms, and medication usage. Subjects completed follow-up evaluations at 12 weeks, and one-and two-year periods. After BT, pre-bronchodilator forced expiratory volume at one second (FEV1) % predicted was maintained with no significant change from baseline at two-year follow-up. Significant increases were observed at 12 weeks (p=0.043) and one year (p=0.030). Post-bronchodilator FEV1 % predicted was maintained throughout the study period, with no significant change from baseline. The prebronchodilator FEV1/forced vital capacity (FVC) ratio was higher at one year than at baseline, but not significant at 12 weeks or two years post-treatment. There was no significant increase in the mean post-bronchodilator FEV1/FVC ratios after treatment. Compared with baseline, the authors report statistically significant improvements in morning and evening peak flows at 12 weeks post-treatment, which is the latest time data were collected by diary (no p values were reported). Regarding symptom-free days there was a statistically significant increase in mean percentage of symptom-free days between baseline and 12 weeks after treatment (p=0.015). Changes from baseline in rescue medication use were not significant (p>0.05). Study design and small patient population limit the ability to extrapolate these findings to the target population.

Technology Assessments/Systematic Reviews:
In a Cochrane systematic review by Torrego et al. (2014) the authors noted that bronchial thermoplasty 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.

In an Emerging Technology Evidence Report titled “Bronchial Thermoplasty for Treating Adult Patients with Severe Persistent Asthma” ECRI (2013) notes the following:

- regarding the benefits of bronchial thermoplasty (BT) plus medical management compared with medical management, ECRI notes BT plus continued medical management results in improved quality of life for patients with severe persistent asthma for up to one year in three RCTs. However, the only trial that blinded patients to their treatment (i.e., AIR2), suggests a partial placebo effect associated with BT. ECRI notes one trial suggests a marginal improvement in quality of life for patients receiving BT compared to sham treatment. Inconsistent results were reported across studies for many other efficacy outcomes, including percentage of symptom-free days, rescue medication use, severe exacerbation rate, and emergency department visits.
- regarding adverse events (AE) associated with BT, ECRI notes that evaluating the long-term safety of BT is important because the procedure alters the amount of smooth muscle, and it is necessary to know whether untoward effects occur over time due to this change.

In a published technology assessment, the California Technology Assessment Forum ([CTAF], 2011) analyzed eight studies relative to the use of bronchial thermoplasty. The CTAF noted that the methodological quality of the randomized clinical trials (RCT) were poor (Pavord, 2007), fair (Cox, 2007), and good (Castro, 2010).

Regarding the Research in Severe Asthma trial ([RISA], Pavord, 2007) the CTAF notes that although there were significant differences favoring the bronchial thermoplasty (BT) group for rescue bronchodilator use, improvements in quality of life, and in asthma control there were large baseline differences between the groups in these three measures, so the findings may be due to regression to the mean or unmeasured confounders not accounted for in the analyses. The CTAF also notes it is difficult to draw meaningful conclusions from the RISA trial given the size, baseline imbalances between the groups, and lack of blinding. Regarding the AIR2 trial (Castro, 2010), the CTAF notes that primary benefits reported include a significant reduction in severe asthma exacerbations and significantly fewer emergency room (ER) visits when events occurring during the treatment period were excluded and results appear stable through two years of follow-up. There was no reduction in hospitalizations and the rate of severe asthma exacerbations over the entire one-year follow-up period was slightly higher in the BT group. In addition, the study did not meet its primary endpoint and there are clear harms during the initial treatment period. The CTAF notes uncertainty regarding whether the risks of three bronchoscopies, three steroid bursts, and the short term increase in asthma exacerbations is balanced by the small improvement in the Asthma Quality of Life Questionnaire (AQLQ) score and the apparent long-term reductions in severe exacerbations and ER visits. Nonetheless the California Technology Assessment Forum (CTAF) panel determined that net health outcomes were improved in patients with severe asthma not adequately controlled by inhaled corticosteroids (ICS) and long-acting beta$_2$ agonist therapy.

U.S. Food and Drug Administration (FDA)
In April 2010, the FDA granted Asthmatx, Inc.(Boston Scientific, Natick, MA) premarketing approval for the Alair® Bronchial Thermoplasty System 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$_2$ agonists. As a condition of approval, Ashmatx must conduct two five-year post approval studies to investigate the system's long-term safety and effectiveness. This requirement includes a continuation of the AIR-2 Trial with longitudinal data on the durability of effectiveness of BT out to five years and a new prospective open-label, single-arm, multi-center study in the U.S. to demonstrate durability of treatment effect and safety out to five years from treatment.

Professional Societies/Organizations
American College of Chest Physicians ([CHEST], 2014): In a 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**.**

European Respiratory Society (ERS)/American Thoracic Society ([ATS], 2014): On behalf of the ERS/ATS, Chung et al. published guidelines on the definition, evaluation and treatment of severe asthma. Regarding bronchial thermoplasty, the quality of evidence is rated as very low. The guidelines recommend that it should be performed in adults with severe asthma only in the context of an Institutional Review Board approved independent systematic registry or clinical study. The ERS/ATS notes this is a strong recommendation because of the low confidence in the currently available estimates of the effects of bronchial thermoplasty in patients with severe asthma. The guideline also notes both potential benefits and harms may be large and the long-term consequences are unknown and notes that studies are needed to define its effects on relevant objective primary outcomes, to better understand the phenotypes of responding patients, its effects in severe obstructive asthma, or in whom systemic corticosteroids are used, and its long-term benefits and safety.

Use Outside of the US
British Thoracic Society (BTS): On behalf of the BTS, Du Rand et al. (2011) published a guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Regarding the use of bronchial thermoplasty the Guideline notes that it is a possible treatment option in selected patients with severe persistent asthma already on maximal therapy, although its place in the treatment of asthma remains to be established. The Guideline also notes that long-term safety and efficacy remain unclear. Hence treatment should be limited to a few specialist centers in carefully selected patients. Longer-term follow-up of treated patients is needed.

Global Initiative for Asthma ([GINA], updated 2014): GINA published an updated guideline in May 2014 titled 'Global Strategy for Asthma Management and Prevention 2014 (Revision).' The guideline recommends bronchial thermoplasty in highly selected adult patients with uncontrolled asthma despite use of recommended therapeutic regimens and referral to an asthma specialty center. Bronchial thermoplasty is a potential treatment option in some countries (Evidence B). The recommendation further notes that caution should be used in

selecting patients for this procedure as the number of studies is small, and people with chronic sinus disease, frequent chest infections or FEV_1 <60% predicted were excluded (Evidence D).

As described in the guideline, “Evidence B consists of randomized, controlled trials and meta-analyses; limited body of data. Evidence is from endpoints of intervention that includes only a limited number of patients, post-hoc or subgroup analysis.” “In general, Category B applies when few randomized trials exist, small in size, undertaken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent.” Evidence D is defined as panel consensus judgment, used only in cases where some guidance is deemed valuable but the clinical literature addressing the subject was insufficient to justify placement in one of the other categories.“

National Institute for Health and Care Excellence (formerly National Institute for Health and Clinical Excellence, [NICE], 2012) published a guideline, titled ‘Bronchial Thermoplasty for Severe Asthma.’ The Guideline notes that 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. NICE notes this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into bronchial thermoplasty for severe asthma. Research outcomes should include objective measurements of lung function, symptom control, medication requirements and quality of life. Long-term safety and efficacy outcomes are particularly important. Regarding safety, the Specialist Advisors considered bronchial stenosis to be a possible complication in the long-term.

Summary
Bronchial thermoplasty (BT) is a minimally invasive technique that has been proposed to treat patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting $beta_2$ agonists. Although there is some published peer-reviewed evidence suggesting improved outcomes with follow-up to five years in selected subsets of individuals with asthma, the ability to determine improved health outcomes is limited by small study populations, which precludes the ability to draw affirmative conclusions and generalize findings to routine clinical practice. Further, an increase in respiratory-related adverse events, including hospitalizations has been noted post treatment with BT. Support by professional societies/organizations in the form of published consensus statements is variable. Although results are promising for a targeted population, data are insufficient to support the safety and long-term effectiveness of bronchial thermoplasty for the treatment of severe, persistent asthma or any indication.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.
3) ICD-10-CM Procedure Codes are for informational purposes only and are not effective until 10/01/2015.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

ICD-9-CM Procedure Codes	Description
32.27	Bronchoscopic bronchial thermoplasty, ablation of smooth airway muscle

ICD-10-CM Procedure Codes (Effective 10/01/2014)	Description
0B538ZZ	Destruction of Right Main Bronchus, Via Natural or Artificial Opening Endoscopic
0B548ZZ	Destruction of Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B558ZZ	Destruction of Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B568ZZ	Destruction of Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B578ZZ	Destruction of Left Main Bronchus, Via Natural or Artificial Opening Endoscopic
0B588ZZ	Destruction of Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B598ZZ	Destruction of Lingula Bronchus, Via Natural or Artificial Opening Endoscopic
0B5B8ZZ	Destruction of Lower Lobe Bronchus, left, Via Natural or Artificial Opening Endoscopic

References

1. American Academy of Allergy, Asthma and Immunology. Conditions dictionary. © 2014 American Academy of Allergy, Asthma, and Immunology. Accessed May 17, 2014. Available at URL address: http://www.aaaai.org/conditions-and-treatments/conditions-dictionary/bronchial-thermoplasty.aspx

2. American College of Chest Physicians. Position payment for coverage and payment bronchial thermoplasty. May 12, 2014. Accessed May 17, 2014. Available at URL address: http://www.chestnet.org/News/CHEST-News/2014/05/Position-Statement-for-Coverage-and-Payment-for-Bronchial-Thermoplasty

3. American Lung Association. Lung disease data; 2008. Accessed May 17, 2014. Available at URL address: http://www.lung.org/assets/documents/publications/lung-disease-data/LDD_2008.pdf

4. Bel EH. Bronchial thermoplasty: has the promise been met? Am J Respir Crit Care Med. 2010 Jan 15;181(2):101-2.

5. Boston Scientific Corporation. Bronchial Thermoplasty™. © 2014 Boston Scientific Corporation. Accessed May 17, 2014. Available at URL address: http://btforasthma.com/

6. California Technology Assessment Forum. Bronchial thermoplasty for the treatment of sever asthma. Published 2011 Oct 19. Accessed May 17, 2014. Available at URL address: http://ctaf.org/assessments?field_condition_tid=6&field_specialty_tid=All&field_met_ctaf_criteria__tid=All&items_per_page=10&=Apply

7. Canadian Agency for Drugs and Technologies in Health (CADTH). Bronchial thermoplasty: a hot approach to asthma treatment? Health Technology Update; issue 6. 2007. Accessed May 17, 2014. Available at URL address: http://www.cadth.ca/media/pdf/hta_thupdate_issue6-page-5_e.pdf

8. Castro M, Musani AI, Mayse ML, Shargill NS. Bronchial thermoplasty: a novel technique in the treatment of severe asthma. Ther Adv Respir Dis. 2010 Apr;4(2):101-16.

9. Castro M, Rubin AS, Laviolette M, Fiterman M, De Andrade LM, Shah PL, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-

blind, sham-controlled clinical trial. Am J Respir Crit Care Med. 2010 Jan 15;181 (2):116-24. Epub 2009 Oct 8.

10. Castro M, Rubin AS, Laviolette M, Hanania Na, Armstrong B, Cox G, AIR2 Trial Study Group. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Ann Allergy Asthma Immunol. 2011 Jul;107(1):65-70. Epub 2011 Apr 14.

11. Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014 Feb;43(2):343-73. Accessed May 14, 2014. Available at URL address: http://www.thoracic.org/statements/resources/allergy-asthma/severe-asthma-full.pdf

12. Cox G, Miller JD, McWilliams A, et al. Bronchial thermoplasty for asthma. Am J Respir Crit Care Med. 2006. 173:965-9.

13. Cox G, Thomson NC, Rubin AS, et al: AIR Trial Study Group. Asthma control during the year after bronchial thermoplasty. N Engl J Med. 2007. 356:1327-37.

14. Diaz-Mendoza J, Bai C, Huang HD, Simoff MJ. Bronchial thermoplasty. Chin Med J (Engl). 2013;126(17):3375-8.

15. Du Rand IA, Barber PV, Goldring J, Lewis RA, Mandal S, Munavvar M, et al. Summary of the British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax. 2011 Nov;66(11):1014-5.

16. ECRI Institute. Alair Bronchial Thermoplasty System (Boston Scientific, Inc.) for Treating Asthma. [Hotline Service]. Plymouth Meeting (PA): ECRI Institute; Published 2014 Jan 3. Available at URL address: http://www.ecri.org.

17. ECRI Institute. Bronchial thermoplasty for treating adult patients with severe persistent asthma. [Emerging technology evidence report]. Plymouth Meeting (PA): ECRI Institute; Published 2013 Aug 15. Available at URL address: http://www.ecri.org.

18. Federal Drug Administration. Alair Bronchial Thermoplasty System-P080032. Summary of safety and effectiveness data. Updated 2010 May 19. Accessed May 17, 2014. Available at URL address: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm212594.htm

19. Federal Drug Administration. FDA approves new device for adults with severe and persistent asthma. Accessed: May 17, 2014. Available at URL address: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm209909.htm

20. Greenberger PA. Asthma. In: Grammer LC, Greenberger PA. Patterson's Allergic diseases, 7th ed. Philadelphia: Lippincott Williams & Wilkins;2009.

21. Kupeli E, Karnak D, Mehta AC. Bronchial thermoplasty. In: Mason RJ, Broaddus VC, Martin TR, King TE, Schraufnagel DE, Murray JF, et al. Murray and Nadel's Textbook of respiratory medicine, 5th ed. Philadelphia: Saunders Elsevier; 2010.

22. Kynyk J, Benninger C, Wood KL. Bronchial thermoplasty. Otolaryngol Clin North Am. 2014 Feb;47(1):77-86.

23. Lugogo N, Que LG, Fertel D, Kraft M. Asthma. In: Mason RJ, Broaddus VC, Martin TR, King TE, Schraufnagel DE, Murray JF, et al. Murray and Nadel's Textbook of respiratory medicine, 5th ed. Philadelphia: Saunders Elsevier; 2010.

24. Michaud G, Ernst A. Counterpoint: efficacy of bronchial thermoplasty for patients with severe asthma. Is there sufficient evidence? Not yet. Chest. 2011 Sep;140(3):576-7; discussion 577.

25. Miller JD, Cox G, Vincic L, Lombard CM, Loomas BE, Dancek CK. A prospective feasibility study of bronchial thermoplasty in the human airway. Chest. 2005 Jun;127(6):1999-2006.

26. Mitzner W. Bronchial thermoplasty in asthma. Allergol Int. 2006 Sep;55(3):225-34.

27. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Bethesda (MD): Global Initiative for Asthma (GINA); May 6, 2014. Accessed May 15, 2014. Available at URL address: http://www.ginasthma.org/

28. National Heart Lung and Blood Institute. Guidelines for the diagnosis and management of asthma. 2007. Accessed May 10, 2014. Available at URL address: http://www.nhlbi.nih.gov/guidelines/current.htm

29. National Institute for Health and Care Excellence (NICE). Bronchial thermoplasty for severe asthma: Consultation document IPG419. 2012. Accessed May 10, 2014. Available at URL address: http://publications.nice.org.uk/bronchial-thermoplasty-for-severe-asthma-ipg419.

30. Pascual RM. Asthma. Med Clin North Am. 2011;95(6):1115-24.

31. Pavord ID, Cox G, Thomson NC, Rubin AS, Corris PA, Siersted HC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic severe asthma. Am J Respir Crit Care Med. 2007 Dec 15;176(12):1185-91.

32. Pavord ID, Thomson NC, Niven RM, Corris PA, Chung KF, Cox G, Armstrong B, Shargill NS, Laviolette M; Research in Severe Asthma Trial Study Group. Safety of bronchial thermoplasty in patients with severe refractory asthma. Ann Allergy Asthma Immunol. 2013 Nov;111(5):402-7.

33. Shifren A, Chen A, Castro M. Point: Efficacy of bronchial thermoplasty for patient s with severe asthma. Is there sufficient evidence? Yes. Chest. Sep;140(3):576-7; discussion 576.

34. Smith ME, Elstad MR. Bronchology. In: Snow, Jr. JB, Wackym PA. Ballenger's otorhinolaryngology head and neck surgery, 17th ed. NY: BC Decker;2009.

35. Thomson NC, Rubin AS, Niven RM, Corris PA, Siersted HC, Olivenstein R, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma intervention research (AIR) trial. BMC Pul Med. 2011 Feb 11;11:8.

36. Torrego A, Solà I, Munoz AM, Roqué I Figuls M, Yepes-Nuñez JJ, Alonso-Coello P, Plaza V. Bronchial thermoplasty for moderate or severe persistent asthma in adults. Cochrane Database Syst Rev. 2014 Mar 3;3:CD009910.

37. Wahidi MM, Kraft M. Bronchial thermoplasty for severe asthma. Am J Respir Crit Care Med. 2012 Apr 1;185(7):709-14. Epub 2011 Nov 10.

38. Wechsler ME, Laviolette M, Rubin AS, Fiterman J, Lapa e Silva JR, Shah PL, et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. J Allergy Clin Immunol. 2013 Dec;132(6):1295-302.

39. Wu Q, Xing Y, Zhou X, Wang D. Meta-analysis of the efficacy and safety of bronchial thermoplasty in patients with moderate-to-severe persistent asthma. J Int Med Res. 2011;39(1):10-22.