



Payer Coverage for Bronchial Thermoplasty

Shifting the Traditional Paradigm for Refractory Asthma Therapy

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The advent of bronchial thermoplasty (BT) provides a novel therapeutic option for asthma refractory to traditional medical therapy. Insurance coverage poses significant frustration for centers performing BT. Although clinical research has provided evidence of the usefulness and long-term safety of BT, establishing “reasonability and necessity” remains a daunting challenge in securing private and governmental insurance coverage. As a result, obtaining coverage poses significant frustration for centers capable of performing BT for patients suffering from severe asthma. Until recently, BT had been categorized by a temporary set of Current Procedural Terminology (CPT) codes as an emerging technology, service, or procedure (category 3). Based on increasing implementation of BT nationwide, the American Medical Association CPT Editorial Panel has assigned category 1 CPT codes for BT in their published 2013 professional edition. It is hoped that such a recommendation will reinforce the medical community’s belief in the usefulness of BT and help facilitate decisions on insurance coverage. The ability to secure coverage for BT through physician advocacy and Centers for Medicare and Medicaid Services support will help move the treatment of refractory asthma forward.

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Abbreviations: AIR = Asthma Intervention Research; BT = bronchial thermoplasty; CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; CTAF = California Technology Assessment Forum; FDA = Food and Drug Administration

Severe persistent asthma is derived from a constellation of processes involving airway inflammation and smooth muscle bronchoconstriction. Individuals suffering from severe persistent asthma are subject to airway hyperresponsiveness triggered by various environmental factors and physiologic defects. Asthma has been described as an allergic disorder, with airway pathophysiology resulting from chronic T helper cell type-2-driven eosinophilic inflammation.¹ Additionally, higher deposition of smooth muscle within airway submucosa, increased expression of contractile proteins,

and amplified activation of smooth muscle contractile units likely contribute to the extreme airway hyperresponsiveness and bronchoconstriction witnessed in severe and fatal asthma.² Identifying effective treatments for patients suffering from severe persistent asthma poses an arduous challenge for physicians. Despite treatment with β_2 -agonists, high-dose inhaled corticosteroids, leukotriene pathway modifiers, and oral corticosteroids, a proportion of patients with severe asthma will continue to suffer from chronic symptoms and frequent exacerbations.^{3,4} As the burden of this disease to governments, health-care systems, families, and patients rises, deaths related to asthma also continue to climb worldwide.⁵ The yearly cost of asthma in the United States was approximately \$3,300 per person with asthma from 2002 to 2007, with medical expenses associated with the disease increasing from \$48.6 billion to \$50.1 billion during the same time period. Additionally, approximately 59% of children and 33% of adults suffering from asthma missed school or work secondary to exacerbations in 2008.⁶

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The advent of bronchial thermoplasty (BT) provides a novel bronchoscopic option for asthma refractory to conventional medical therapy. The procedure involves three separate bronchoscopic procedures 2 weeks apart using the Alair System (Boston Scientific) and a conventional flexible bronchoscope. During the procedure, radiofrequency energy is directed toward segmental airways with the goal of manipulating bronchial smooth muscle mass by thinning airway muscle fibers without actually burning tissue.⁷ The use of BT achieves clinical improvement by reducing the contractile function of airway smooth muscle, thus attenuating airway hyperresponsiveness and bronchoconstriction.^{8,9} Evidence supporting the clinical success of BT, along with long-term safety data, continues to solidify the importance of the procedure as contemporary asthma therapy.¹⁰⁻¹² Based on the prevalence of smooth muscle hypertrophy in the pathophysiology of severe asthma, BT provides a sound treatment option for patients whose asthma cannot be controlled by conventional medical therapy.

A number of high-profile human trials have substantiated the therapeutic success of BT. Trials such as the Asthma Intervention Research (AIR) trial, the Research in Severe Asthma (RISA) trial, and the AIR-2 trial provide evidence of an acceptable complication profile, an improvement in quality of life, and a reduction in health-care use in patients treated with BT.¹⁰⁻¹² Notably, the AIR-2 trial incorporated a sham control and revealed a significant reduction in severe exacerbations, ED visits, and a clinically meaningful improvement in the Asthma Quality of Life Questionnaire from baseline at an average of 6, 9, and 12 months.¹² Although these trials did not uncover a significant improvement in pulmonary function, they did provide evidence of significant symptomatic improvement following BT. Additionally, studies describing stable pulmonary function 5 years after BT have been published, further supporting the procedure's safety and sustainability.¹³ This body of data reinforcing clinical improvement and spirometric stability was essential in paving the road toward the Food and Drug Administration's (FDA's) approval of the use of BT for refractory asthma in 2010. Equally as important, such research has driven most pulmonologists to establish BT as a reasonable and necessary procedure, two descriptors essential for private and governmental insurers to support this new technology.

Despite FDA approval, evidence of persistent effectiveness 2 years after treatment, and 5 years of safety data in a well-defined patient population, difficulty with securing insurance coverage for patients needing BT represents a significant source of frustration for patients. Physicians frequently struggle with both private and governmental insurers to obtain approval for BT, despite evidence that the procedure yields clin-

ical benefits. When BT was first introduced as the first procedure-based treatment of refractory asthma, Medicare continued to struggle with the designation of "reasonable and necessary" and no commercial coverage policies were established. In fact, in 2007, 3 years prior to FDA approval, multiple private insurers had already posted investigational/experimental noncoverage policies for BT. Furthermore, within 1 year after FDA approval, most other private payers had adopted similar noncoverage policies. Multiple commercial payers have continued to invoke a need for further data collection, technology assessments, and specialty society statements supporting the safety and efficacy of BT before they are willing to institute coverage. Along these lines, BT was listed originally with a temporary set of Current Procedural Terminology (CPT) codes (0276T and 0277T) as an emerging technology, service, or procedure (category 3). The principal purpose of category 3 codes is to allow for data collection and for tracking of new procedures, often in an effort to establish universal application and to provide documentation in an effort to gain FDA approval. Conversely, category 1 CPT codes represent procedures that are consistent with contemporary medical practice and are recognized by all public and private health insurance payers in the United States. Criteria to gain category 1 status include FDA approval, nationwide performance by health-care professionals, and proof of the clinical efficacy procedure,¹⁴ all current characteristics of BT.

Current coverage policies governed by the Centers for Medicare and Medicaid Services (CMS) are appropriately driven by legislation requiring that coverage be based on items and services that are deemed to be "reasonable and necessary." Understandably, defining "reasonable and necessary" continues to be complex and challenging because a number of clinical, research, and risk/benefit considerations accompany such a determination. Past determinations of "reasonable and necessary" involved review by local contractors who had an understanding of new services or technology. Unfortunately, as medical advancement and technologic innovation progressed, coverage for similar treatments varied according to locality. Such variability in coverage approval led to the formal National Coverage Determination process to guide coverage decisions. Unfortunately, understanding the definition of "reasonable and necessary" by CMS continues to be elusive. The Coverage with Evidence Development policy developed from an attempt to resolve this issue, which allows Medicare to provide conditional coverage for certain medical technology as further safety and efficacy data are collected.

As a result of the difficulty in defining "reasonable and necessary," pulmonary physicians and interventional pulmonologists at tertiary care medical centers

are often faced with multiple, lengthy appeal processes to obtain coverage approval, which is far from guaranteed. The appeal process typically requires a request for individual case review prior to BT, to establish medical necessity through a predetermination of benefits. Such a request requires the insurer to review all of the patient's clinical information to justify an exception to their noncoverage policy. The essential elements for establishing medical necessity include the correct diagnosis of asthma, along with use of best care to treat the disorder for an appropriate amount of time with failure of disease control. If insurance companies are willing to approve BT through a predetermination of benefits, persistence on the part of the physician is required. Per data collected by Boston Scientific, in 2011 approximately 40% of requests were approved by insurers on first request, with an improvement to 60% in 2012 (Kelly Shriner, VP of Reimbursement, Boston Scientific, written communication, November 2012). In addition to physician efforts, Boston Scientific aids in the appeal process by offering Health Insurance Portability and Accountability Act (HIPPA)-compliant third-party resources to facilitate collection of required predetermination medical records and by providing follow-up with payers on the physician's behalf until a determination is made.

Although most pulmonologists consider BT "reasonable and necessary" based on clinical improvement and long-term safety, physicians typically view insurance companies as not only failing to see the health benefits of BT, but also failing to appreciate the cost-effectiveness resulting from fewer hospital admissions for asthma exacerbations. It is difficult to assess the exact cost of BT based on its relative infancy as a therapeutic procedure, but it is believed to cost tens of thousands of dollars per procedure.¹⁵ Additionally, the three Alair catheters needed to perform BT cost approximately \$1,500 each. Finally, purchase of the Alair system costs close to \$30,000. Although this equipment appears costly at first glance, the CMS agreed to pay for the Alair catheter in 2012 and the one-time cost of a BT system is quite modest compared with the cost of other equipment used by interventional pulmonologists. Additionally, these costs pale in comparison with the estimated direct costs of asthma, which include the nearly \$10 billion in direct costs and the \$8 billion lost from indirect costs.¹⁶ Expectedly, the largest direct costs of asthma are those allocated to inpatient hospitalizations, accounting for anywhere from 47% to 86% of total direct costs.¹⁷

The road toward coverage for BT has remained difficult since FDA approval in 2010, but it is hoped that recent changes in policy will make coverage and availability of the procedure less problematic. Based on the increasing popularity and the growing implementation of BT nationwide, the American College of

Chest Physicians and the American Thoracic Society have led a campaign to adjust CPT coding for BT. As a result, the American Medical Association Editorial Panel has assigned category 1 CPT codes for BT in their published CPT 2013 Professional Edition.¹⁸ Beginning January 1, 2013, Medicare will recognize two new outpatient CPT codes for BT (31660 and 31661) as eligible for payment for the treatment of Medicare beneficiaries with severe, persistent asthma. After Medicare has sufficient information to determine total procedural costs, BT will be assigned the most appropriate payment group for the procedure and then the pass-through payment option will be retired.¹⁹ This new categorization represents a step toward acknowledging the efficacy and safety of BT in patients suffering from refractory asthma, helping to facilitate claims processing and hopefully pave the way toward private payer coverage.

The benefits of BT have also been corroborated by a number of third-party assessors, including the California Technology Assessment Forum (CTAF). The CTAF serves as a forum aimed at assessing new and emerging medical technology, and it strives for objectivity and transparency. Additionally, the CTAF assessment criteria are similar to those used by the Blue Cross Blue Shield Technology Evaluation Center, another highly respected assessing body commonly referenced by private insurers to create their own coverage policies. In March 2012, the CTAF panel on BT concluded that BT meets safety and efficacy status by filling the following criteria: (1) final approval from the appropriate government regulatory bodies, in this case the FDA, has been received; (2) there is scientific evidence describing the effectiveness of the technology regarding health outcomes; (3) net health outcomes are improved; (4) it is as beneficial as any established alternative therapy; and (5) the associated improvement from the procedure is attainable outside of investigational settings.²⁰ It is hoped that such endorsements from reputable third-party groups, along with the development of category 1 CPT coding by the CMS, will facilitate recognition of the importance of BT for patients with severe asthma.

The use of BT represents an evolution in the traditional paradigm for treating severe persistent asthma. This novel procedure provides therapy for patients suffering from the debilitating symptoms of asthma that are refractory to medical therapy. In light of the mounting evidence of the effectiveness and safety of the procedure, CMS has taken the appropriate steps to make BT more accessible to suitable patients by establishing category 1 CPT codes. With the support of the medical community, along with the backing of the CMS, significant steps have been taken to make insurance approval for BT closer to reality. Further benefit toward patient care would be seen not only

to help define the designation of “reasonable and necessary,” but also to clearly establish both clinical and spirometric criteria for BT coverage. Although the progression toward approval has been slow, it is only a matter of time before BT is recognized as an essential step in the treatment approach to severe persistent asthma.

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REFERENCES

- Galli S, Tsai M, Piliponsky A. The development of allergic inflammation *Nature*. 2008;454(7203):445-454.
- Woodruff PG, Dolganov GM, Ferrando RE, et al. Hyperplasia of smooth muscle in mild to moderate asthma without changes in cell size or gene expression. *Am J Respir Crit Care Med*. 2004;169(9):1001-1006.
- Backman KS, Greenberger PA, Patterson R. Airways obstruction in patients with long-term asthma consistent with ‘irreversible asthma. *Chest*. 1997;112(5):1234-1240.
- Chung KF, Godard P, Adelroth E, et al; European Respiratory Society. Difficult/therapy-resistant asthma: the need for an integrated approach to define clinical phenotypes, evaluate risk factors, understand pathophysiology and find novel therapies. ERS Task Force on Difficult/Therapy-Resistant Asthma. *Eur Respir J*. 1999;13(5):1198-1208.
- Akinbami L, Moorman J, Bailey C, et al. *Trends in Asthma Prevalence, Health Care Use, and Mortality in the United States, 2001-2010*. NCHS Data Brief; 2012:94.
- Asthma in the US. Centers for Disease Control and Prevention website. <http://www.cdc.gov/vitalsigns/asthma/>. Published 2011. Accessed January 4, 2013.
- Lombard C, Vincic L, Cox G, et al. Histologic effects of bronchial thermoplasty of canine and human airways. *Am J Respir Crit Care Med*. 2002;165:A779.
- Danek CJ, Lombard CM, Dungworth DL, et al. Reduction in airway hyperresponsiveness to methacholine by the application of RF energy in dogs. *J Appl Physiol*. 2004;97(5):1946-1953.
- Cox PG, Miller J, Mitzner W, Leff AR. Radiofrequency ablation of airway smooth muscle for sustained treatment of asthma: preliminary investigations. *Eur Respir J*. 2004;24(4):659-663.
- 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(13):1327-1337.
- Pavord ID, Cox G, Thomson NC, et al; RISA Trial Study Group. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med*. 2007;176(12):1185-1191.
- Castro M, Rubin AS, Laviolette M, 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;181(2):116-124.
- Thompson N, Rubin A, Niven R, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. 2011;11:8.
- American Medical Association. CPT® process: how a code becomes a code. American Medical Association website. <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-process-faq/code-becomes-cpt.page>. Accessed January 4, 2013.
- Wahidi MM, Kraft M. Bronchial thermoplasty for severe asthma. *Am J Respir Crit Care Med*. 2012;185(7):709-714.
- The cost of asthma. Asthma and Allergy Foundation 1992 and 1998 study, 2000 update. Asthma and Allergy Foundation website. <http://www.aafa.org/display.cfm?id=9&sub=42#over>. Accessed January 4, 2013.
- Bahadori K, Doyle-Waters M, Marra C, Lynd L, Alasaly K. Economic burden of asthma: a systemic review. *BMC Pulm Med*. 2009;9:24.
- CPT 2013 Professional Edition*. First ed. Chicago, IL: American Medical Association; 2012.
- Coding & billing quarterly. *ATS Coding and Billing Quarterly*. Newsletter. New York, NY: American Thoracic Society; 2012; 3-4.
- Tice, J. Bronchial thermoplasty for the treatment of severe asthma [data file]. San Francisco, CA. California Technology Assessment Forum web site. http://ctaf.org/sites/default/files/assessments/1381_file_BTSevereAsthma_W4.pdf. Published 2011. Accessed January 4, 2013.