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OVERVIEW

Bronchial thermoplasty is a potential treatment option for patients with severe persistent asthma. It consists of radiofrequency energy delivered to the distal airways with the aim of decreasing smooth muscle mass believed to be associated with airway inflammation.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Bronchial thermoplasty for the treatment of asthma is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Bronchial thermoplasty for the treatment of asthma is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL CRITERIA

Not applicable

BACKGROUND

Asthma

Asthma, a chronic lung disease, affects approximately 8.3% of adults and 8.3% of children in the U. S. and, in 2017, accounted for approximately 1.7 million emergency department visits and 3615 deaths.¹ Asthma symptoms include episodic shortness of breath that is generally associated with other symptoms such as wheezing, coughing, and chest tightness. Objective clinical features include bronchial hyperresponsiveness, airway inflammation, and reversible airflow obstruction (at least 12% improvement in forced expiratory volume in 1-second post-bronchodilator, with a minimum of 200 mL improvement). However, there is substantial heterogeneity in the inflammatory features of patients diagnosed with asthma, and this biologic diversity is responsible, at least in part, for the variable response to treatment in the asthma population.

Management

Management of asthma consists of environmental control, patient education, management of comorbidities, and regular follow-up for affected patients, as well as a stepped approach to medication treatment. Guidelines from the National Heart, Lung and Blood Institute have defined six pharmacologic steps: step 1 for intermittent asthma and steps 2 through 6 for persistent asthma. The preferred daily medications: step 1: short-acting b-agonists as-needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting bagonists (LABA) or medium-dose ICS; step 4: medium-dose ICS and LABA; step 5: high-dose ICS and LABA; and step 6: high-dose ICS and LABA, and oral corticosteroids.

Despite this multidimensional approach, many patients continue to experience considerable morbidity. In addition to ongoing efforts to implement optimally standard approaches to asthma treatment, new therapies are being developed. One recently developed therapy is bronchial thermoplasty, the controlled delivery of

radiofrequency energy to heat tissues in the distal airways. Bronchial thermoplasty is based on the premise that patients with asthma have an increased amount of smooth muscle in the airway and that contraction of this smooth muscle is a major cause of airway constriction. The thermal energy delivered via bronchial thermoplasty aims to reduce the amount of smooth muscle and thereby decrease muscle-mediated bronchoconstriction with the ultimate goal of reducing asthma-related morbidity. A typical full course of treatment consists of 3, one hour sessions, given 3 weeks apart under moderate sedation. All accessible airways distal to the main stem bronchus that are 3 to 10 mm in diameter are treated once, except those in the right middle lobe; the lower lobes are treated first followed by the upper lung. Bronchial thermoplasty is intended for consideration as a supplemental treatment for patients with severe persistent asthma (ie, steps 5 and 6 in the stepwise approach to care).

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes three randomized controlled trials (RCTs) and observational studies. The relevant outcomes are symptoms, quality of life (QOL), hospitalizations, and treatment-related morbidity. Early studies (RISA, AIR) investigated safety outcomes, finding similar rates of adverse events and exacerbations between the bronchial thermoplasty and control groups. These trials were limited by their lack of sham control. The AIR2 trial is the largest of the three published RCTs, and the only one double-blinded and sham-controlled, with sites in the U. S. Over one year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome of mean change in the QOL score but was found to be superior on a related outcome, improvement in the QOL of at least 0.5 points on the Asthma Quality of Life Questionnaire. There was a high response rate in the sham group of the AIR2 trial, suggesting a large placebo effect, particularly for subjective outcomes such as QOL. There are no long-term sham-controlled efficacy data. Findings on adverse events from the three trials have suggested that bronchial thermoplasty is associated with a relatively high rate of adverse events, including hospitalizations during the treatment period, but not in the posttreatment period. Safety data up to five years have been reported in the RCTs for patients treated with bronchial thermoplasty but not for control patients. Safety data from a U.K. registry study, published in 2016, found that 20% of bronchial thermoplasty procedures were associated with a safety event (ie, procedural complications, emergency respiratory readmissions, emergency department visits, and/or postprocedure overnight stays). Conclusions cannot be drawn about the effect of bronchial thermoplasty on the net health outcome due to the limited amount of sham-controlled data (one RCT) on short-term efficacy, the uncertain degree of treatment benefit in that single sham-controlled trial, the lack of long-term sham-controlled data in the face of a high initial placebo response, and the presence of substantial adverse events. Also, there is a lack of data on patient selection factors for this procedure and, as a result, it is not possible to determine whether there are patient subgroups that might benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

CODING

The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, October 2021
Provider Update, August 2020
Provider Update, October 2019
Provider Update, May 2018
Provider Update, January 2018

REFERENCES

1. Centers for Disease Control & Prevention, National Center for Health Statistics. Asthma. 2018; <https://www.cdc.gov/nchs/fastats/asthma.htm>. Accessed May 28, 2020.
2. National Heart Lung and Blood Institute. Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2012; <https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma>. Accessed May 28, 2020.
3. Global Initiative for Asthma (GINA). Pocket Guide for Asthma Management and Prevention (for Adults and Children Older than 5 Years). April 2021; <https://ginasthma.org/wp-content/uploads/2021/04/Main-Pocket-Guide-2021-FINAL-WM.pdf>. Accessed May 6, 2021.
4. Grant MD. Bronchial thermoplasty for treatment of inadequately controlled severe asthma. *Technol Eval Cent Assess Program Exec Summ*. Mar 2015; 29(12): 1-5. PMID 25962190
5. Pavord ID, Cox G, Thomson NC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med*. Dec 15 2007; 176(12): 1185-91. PMID 17901415
6. Pavord ID, Thomson NC, Niven RM, et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. *Ann Allergy Asthma Immunol*. Nov 2013; 111(5): 402-7. PMID 24125149
7. Cox G, Thomson NC, Rubin AS, et al. Asthma control during the year after bronchial thermoplasty. *N Engl J Med*. Mar 29 2007; 356(13): 1327-37. PMID 17392302
8. Thomson NC, Rubin AS, Niven RM, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. Feb 11 2011; 11: 8. PMID 21314924
9. Castro M, Rubin A, Laviolette M, et al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. *Ann Allergy Asthma Immunol*. Jul 2011; 107(1): 65-70. PMID 21704887
10. Wechsler ME, Laviolette M, Rubin AS, et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. *J Allergy Clin Immunol*. Dec 2013; 132(6): 1295-302. PMID 23998657
11. Chaudhuri R, Rubin A, Sumino K, et al. Safety and effectiveness of bronchial thermoplasty after 10 years in patients with persistent asthma (BT10+): a follow-up of three randomised controlled trials. *Lancet Respir Med*. May 2021; 9(5): 457-466. PMID 33524320
12. 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*. Jan 15 2010; 181(2): 116-24. PMID 19815809
13. Chupp G, Laviolette M, Cohn L, et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies. *Eur Respir J*. Aug 2017; 50(2). PMID 28860266
14. Burn J, Sims AJ, Keltie K, et al. Procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics. *J Asthma*. Oct 2017; 54(8): 872-879. PMID 27905828
15. Burn J, Sims AJ, Patrick H, et al. Efficacy and safety of bronchial thermoplasty in clinical practice: a prospective, longitudinal, cohort study using evidence from the UK Severe Asthma Registry. *BMJ Open*. Jun 19 2019; 9(6): e026742. PMID 31221880
16. Global Initiative for Asthma (GINA). A GINA Pocket Guide for Health Professionals. Difficult-to-Treat & Severe Asthma in Adolescents and Patients: Diagnosis and Management [V2.0]. April 2019; <https://ginasthma.org/wp-content/uploads/2019/04/GINA-Severe-asthma-Pocket-Guide-v2.0-wms-1.pdf>. Accessed May 7, 2021.

17. American College of Chest Physicians (ACCP). Position Statement for Coverage and Payment for Bronchial Thermoplasty. 2014; <http://www.chestnet.org/News/CHEST-News/2014/05/Position-Statement-for-Coverage-and-Payment-for-Bronchial-Thermoplasty>. Accessed May 28, 2020.
18. National Institute for Health and Care Excellence. Bronchial thermoplasty for severe asthma. Interventional procedures guidance [IPG635]. 2018 <https://www.nice.org.uk/guidance/ipg635>. Accessed May 28, 2020.
19. Cloutier MM, Baptist AP, Blake KV, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol*. Dec 2020; 146(6): 1217-1270. PMID 33280709
20. D'Anci KE, Lynch MP, Leas BF, et al. Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 Dec. Report No.: 18-EHC003-EF. PMID: 29659226.

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