Medical Coverage Policy | Bronchial Thermoplasty

EFFECTIVE DATE: 02|03|2015
POLICY LAST UPDATED: 06|21|2023

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.

MEDICAL CRITERIA
Not applicable

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 that the technology results in an improvement in the net health outcome.

Commercial Products
Bronchial thermoplasty for the treatment of asthma is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

BACKGROUND
Asthma
Asthma, a chronic lung disease, affects approximately 8.4% of adults and 5.8% of children in the United States (U.S.). As of 2018, 14.3% of Black children under 18 in the U.S. had asthma, followed by 8% of Hispanic children, 5.6% of White children, and 3.6% of Asian children. In the U.S., the burden of asthma falls disproportionately on Black, Hispanic, and American Indian/Alaska Native individuals; these groups have the highest rates, deaths, and hospitalizations. Compared to White Americans, Black Americans are 1.5 times more likely to have asthma, and Puerto Rican Americans are almost 2 times more likely to have asthma. In 2018 and 2020, asthma exacerbations accounted for approximately 1.6 million emergency department visits and 4145 deaths overall, respectively. Black Americans are 5 times more likely than White Americans to visit the emergency department for asthma and 3 times more likely to die from asthma. 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. A focused update in 2020 addressed the use of add-on long-acting antimuscarinic agents (LAMA), immunotherapy, and bronchial thermoplasty.

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 shamcontrolled 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

Medicare Advantage Plans and Commercial Products

The following CPT code(s) 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, August 2023
Provider Update, October 2022
Provider Update, October 2021
Provider Update, August 2020
Provider Update, October 2019

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