I. Description
Asthma management consists of a multidimensional approach. In spite of this, many patients continue to experience considerable morbidity. Bronchial thermoplasty (BT) is a potential treatment option for patients with poorly controlled severe persistent asthma. It 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, thereby decreasing muscle-mediated bronchoconstriction, with the ultimate goal of reducing asthma-related morbidity.

Bronchial thermoplasty is performed on an outpatient basis. During the procedure, a standard flexible bronchoscope is placed through the patient’s mouth or nose and advanced into the most distal targeted airway. Then, a catheter is advanced through the working channel of the bronchoscope and delivers radiofrequency energy. A course of treatment consists of three separate procedures targeting different regions of the lung.

II. Criteria/Guidelines
Bronchial thermoplasty (BT) is covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:

A. The patient has been managed by an asthma specialist (pulmonologist, allergist, immunologist) for at least six months prior to consideration of BT

B. There is documentation that the patient is compliant with maximum preferred asthma medications, and has received training in asthma self-management (e.g., self-monitoring of symptoms and/or PEF, written asthma action plan, and regular medical review) but has failed therapy, and is at Step 5 or Step 6 of NHLBI/NAEPP (National Heart Lung and Blood Institute/National Asthma Education and Prevention Program) Guidelines, which includes:
   1. Documented current use of an inhaled corticosteroid for at least six consecutive months; and
   2. Documented current use of a long-acting beta agonist or leukotriene inhibitor for at least six consecutive months; and
3. Treatment has not been effective or is not tolerated, as evidenced by at least one of the following:
   a. Poor symptom control as evidenced by the presence of greater than or equal to three of the following:
      1. Daytime asthma symptoms more than twice per week
      2. Any night waking due to asthma
      3. Need for symptoms relief more than twice per week
      4. Any activity limitation due to asthma
   b. Asthma Control Questionnaire (ACQ) score consistently greater than 1.5
   c. Asthma Control Test (ACT) less than 20
   d. Frequent severe exacerbations with the past 12 months (e.g., more than two exacerbations requiring oral corticosteroids)
   e. Two or more serious attacks, hospitalizations, ED visits, or exacerbations requiring systemic corticosteroids within the past 12 months
C. The patient has been diagnosed with chronic, severe persistent asthma and continues to have one or more of the following:
   1. Symptoms occur throughout each day;
   2. Nighttime symptoms occur often, sometimes every night;
   3. Daily physical activities are extremely limited;
   4. Forced expiratory volume in one second (FEV1) is less than 60% predicted
   5. Need for short-acting beta agonists for symptom relief several times per day
D. The patient has a history of symptoms consistent with asthma (e.g., episodic cough, wheezing, or dyspnea provoked by typical triggers) and has reversible expiratory airflow obstruction or positive broncho-provocation testing;
E. The patient is 18 years of age or older;
F. The patient is not a current or recent (i.e., within 12 months) smoker, including e-cigarettes;
G. The patient has not been diagnosed with COPD;
H. The patient is not a candidate for, or has failed a six-month trial with anti-IgE therapy (e.g., omalizumab).
I. The patient is taking, or being considered for, chronic oral corticosteroids to maintain asthma control.
J. Forced expiratory volume in one second (FEV1) is not less than 50% of predicted when optimally treated.

III. Limitations
   A. One complete thermoplasty procedure must be performed in three treatment sessions with a recovery period of 3 weeks or longer between sessions.
   B. Repeat procedures of bronchial thermoplasty, beyond the initial three treatments are not covered because it has not been shown to improve long-term health outcomes.
   C. Bronchial thermoplasty is not covered for any other indications than outlined in criteria.
   D. Bronchial thermoplasty must be performed by clinicians experienced in bronchoscopy and who have completed bronchial thermoplasty training.
IV. Administrative Guidelines

Precertification is required. To precertify complete HMSA's Precertification Request and mail or fax the form as indicated along with the following documentation from the patient’s medical record:

A. Documentation from the medical record showing a six month history of symptoms and treatment by a pulmonologist, allergist, or immunologist, which includes allergy test results and IgE as outlined in criteria (lung function tests, activity level, ACQ, ACT, etc.)

B. Pulmonary test results demonstrating the patient has reversible airway obstruction or has had positive broncho-provocation testing and a definitive diagnosis of chronic, severe persistent asthma

C. Previous medication history showing adherence as well as allergy, intolerance or ineffective drug treatment

D. Documentation the patient is tobacco free and that there are no additional heart implications

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<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tr>
<td>31660</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe</td>
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<tr>
<td>31661</td>
<td>with bronchial thermoplasty, 2 or more lobes</td>
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V. Scientific Background

Early studies in animals and humans showed that the delivery of thermal energy was effective in reducing airway smooth muscle mass. The FDA approved the device in 2010. The first clinical trial evaluating the safety of bronchial thermoplasty enrolled 16 patients with mild to moderate asthma. BT was well tolerated, with all procedure-related events occurring in the first week following the procedure. The AIR trial was an unblinded, multicenter randomized controlled study of BT. A total of 112 patients with moderate-to-severe persistent asthma were enrolled. It showed that treatment with BT resulted in significant improvement in asthma symptoms as measured by symptom-free days and scores of the asthma control questionnaire. Additionally, there was a significant reduction in mild exacerbations and increases in morning peak expiratory flow rate in patients treated with BT. The RISA trial was designed to evaluate the safety and efficacy of BT in patients with severe, symptomatic asthma. Thirty-two patients with severe persistent asthma were enrolled in this unblinded randomized controlled study, which showed significant improvements in asthma symptoms and quality of life in patients treated with BT. The AIR-2 trial was performed using a multicenter, randomized, double blind, sham-controlled design; 288 subjects were enrolled. It showed that patients treated with BT experienced an increase in asthma quality of life scores, as well as a reduced number of asthma exacerbations, emergency department visits, and days lost from work/school. Also, a long-term (i.e., five year) follow-up study showed that patients treated with BT exhibited improvements in airway hyper-responsiveness out to three years, decrease in respiratory-related emergency department visits and hospitalization, reduction in severe exacerbations, and no increased incidence of adverse events (e.g., deterioration of pulmonary function or structural lung changes seen on imaging).
The 2014 Global Initiative for Asthma (GINA) guidelines suggest that “for 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 (Grade B evidence)”. The American College of Asthma, Allergy, and Immunology (ACAAI) states, “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”. The American College of Chest Physicians states, “Bronchial thermoplasty offers treatment for patients with severe asthma who continue to be symptomatic despite maximal medical treatment. We believe the literature supports bronchial thermoplasty as a therapeutic option for patients with severe asthma”. The 2014 European Respiratory Society and American Thoracic Society (ETS/ARS) guidelines on definition, evaluation, and treatment of severe asthma state: “We recommend that bronchial thermoplasty is performed in adults with severe asthma only in the context of an institutional review board approved independent registry or a clinical study.”

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

4. Bronchial thermoplasty for asthma. *Medical Letter on Drugs and Therapeutics.* 2010; 52(1345):65


