Bronchial Thermoplasty

I. Description
Bronchial thermoplasty (BT) is a bronchoscopic treatment, using radiofrequency energy, for patients with severe asthma who remain symptomatic despite optimal medical therapy. Studies have shown BT to be safe and effective in reducing severe exacerbations, improving quality of life, and decreasing emergency department visits. Five-year follow-up studies have provided evidence of continued improvement of health outcomes for BT-treated patients. The Global Initiative for Asthma (GINA) guidelines state that BT can be considered as a treatment option for adult asthma patients at step 5.

Careful patient selection requires close collaboration between the interventional pulmonologist and asthma specialist to ensure continued improvement of healthcare outcomes for patients undergoing bronchial thermoplasty. BT therapy is delivered in three separate sessions at least 3 weeks apart. Different regions of the lung are treated in each of three sessions. Three days prior to starting treatment, patients are treated with 50 mg/day of prednisolone or equivalent for 5 days, starting treatment 3 days prior to the procedure, which is performed under moderate-to-deep sedation or general anesthesia.

Bronchial Thermoplasty uses temperature-controlled radiofrequency energy to remodel the airway and reduce excessive airway smooth muscle, which has been recognized as a predominant feature of asthma. The treatment should be performed in a systemic manner, starting at the most distal part of the (sub)segmental airway, then moving proximally to the main bronchi, ensuring that the majority of the airways are treated. In general, 40-70 RF activations are provided in the lower lobes, and between 50 and 100 activations in the upper lobes combined. The main periprocedural adverse events are exacerbation of asthma symptoms and increased cough and sputum production. Occasionally, atelectasis has been observed following the procedure.

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, instruction for correct inhaler usage, and regular medical review) but has failed therapy, and is at Step 5 of NHLBI/NAEPP (National Heart Lung and Blood Institute/National Asthma Education and Prevention Program) Guidelines, which includes:

1. Documented current use of a high-dose inhaled corticosteroid with long-acting beta2 agonist for at least six consecutive months; and
2. The patient has failed a six-month trial with leukotriene receptor antagonist and all biologics for which he/she is a candidate (e.g., anti-IgE therapy, anti-IL-5, anti-IL-4 receptor subunit alpha)

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:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Need for symptoms relief more than twice per week
      iv. 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. 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 greater than or equal to 4 times per week
   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 does not have cardiovascular disease including myocardial infarction, angina, cardiac dysfunction, cardiac dysrhythmia, conduction defect, cardiomyopathy or stroke.

I. 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.
   E. Patients on chronic oral corticosteroids at a dose > 10 mg. of prednisone equivalent per day are not candidates for bronchial thermoplasty as it is not known to improve health outcomes.

IV. Administrative Guidelines
   Precertification is required. To precertify complete HMSA's Precertification Request and mail or fax the form, or use iExchange 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).

Note that AIR-2 and the PAS2 trials excluded asthmatics with FEV1 <60% and post-bronchodilator FEV1 <65%, the RISA trial excluded those with FEV1<50%. AIR2 and PAS2 also excluded asthmatics requiring >10 mg prednisone daily. Bronchial thermoplasty is associated with a short-term increase in asthma related morbidity, including wheezing, cough, and chest discomfort. Reports of acute postoperative inflammation and pulmonary consolidations on imaging extending beyond treated airways, pulmonary abscess, pulmonary pseudoaneurysm, and massive hemoptysis have also been reported.

The Global Initiative for Asthma (GINA) 2019 guidelines suggest bronchial thermoplasty as a potential treatment option at Step 5 “for adult patients whose asthma remains uncontrolled despite optimization of asthma therapy and referral to a severe asthma specialty center”. “Caution should be used in selecting patients for this procedure. The number of studies is small, people with chronic sinus disease, frequent
chest infections, or FEV1 <60% predicted were excluded from the pivotal sham-controlled study, and patients did not have their asthma treatment optimized before bronchial thermoplasty was performed”. “Bronchial thermoplasty should be performed in adults with severe asthma only in the context of an independent Institutional Review Board-approved systematic registry or a clinical study, so that further evidence about effectiveness and safety of the procedure can be accumulated”.

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.”

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (2012) published guidance on bronchial thermoplasty for severe asthma. The guidance stated: “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.

**Asthma Questionnaires**
The AQLQ is a validated tool that measures the functional problems that are most troublesome to adults with asthma. The questionnaire consists of 32 questions in four domains: symptoms, activity limitation, emotional function, and environmental stimuli. Individuals rate their own levels of impairment from seven (not impaired at all) to one (severely impaired). Higher AQLQ scores represent greater functionality.

The ACQ is another validated instrument that measures overall asthma control, including minimization of symptoms, activity limitation, bronchoconstriction, and rescue medication use. The ACQ has seven sections: five pertaining to universal symptoms of asthma (i.e., awakened at night by symptoms, wake in the mornings with symptoms, limitation of daily activities, shortness of breath, and wheezing), one pertaining to daily rescue bronchodilator use, and one for FEV1. Individuals score five questions from zero (no impairment) to six (maximum impairment) and daily rescue bronchodilator use from zero (no use) to six (greater than 16 puffs most days). Forced expiratory volume in one second is rated from zero (greater than 95 percent predicted) to six (less than 50 percent predicted). A final ACQ score is between zero (well controlled) and six (severely uncontrolled).

The validated Asthma Control Test (ACT ) includes four symptom/reliever questions plus a self-assessed level of control. The ACT assesses the frequency of shortness of breath and general asthma symptoms, use of rescue medications, the effect of asthma on daily functioning, and overall self-assessment of asthma control. The scores range from five (poor control of asthma) to 25 (complete control of asthma), with higher scores reflecting greater asthma control. An ACT score greater than 19 indicates well-controlled asthma.
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


