MEDICAL POLICY

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

Original Issue Date (Created):	**9/1/2011**
Most Recent Review Date (Revised):	**6/2/2020**
Effective Date:	**2/1/2021**

I. POLICY

Bronchial thermoplasty performed in a series of three treatment sessions with a recovery period of three weeks or longer between sessions may be considered **medically necessary** when **all** of the following criteria are met:

- Has chronic, severe persistent asthma
- Has been managed by an asthma specialist (e.g., pulmonologist, allergist/immunologist) for at least six months prior to consideration for bronchial thermoplasty
  - Asthma specialist ensures that individual education, environmental factors, comorbidities and the exclusion of other possible diagnoses (e.g., gastroesophageal reflux disease [GERD], obstructive sleep apnea [OSA], allergic rhinitis, vocal cord dysfunction, chronic obstructive pulmonary disease [COPD], congestive heart failure, obesity, rhinosinusitis, anxiety/depression), have been considered in the management of the individual's severe persistent asthma
- Manifests the following characteristics, despite appropriate use of asthma controller medications:
  - Daily symptoms (e.g., coughing, wheezing, chest tightness, shortness of breath)
  - Night time awakenings, every night
  - Use of rescue medication several times per day
  - Normal activities are extremely limited
- Has a pre-bronchodilator forced expiratory volume in one second [FEV1] greater than 50 percent of predicted value
- Asthma is refractory to either high-dose inhaled corticosteroids (greater than 1000 mcg beclomethasone per day or equivalent) and long-acting beta-agonists (at least 100 mcg salmetrol per day or equivalent), or chronic oral corticosteroids (at a dosage of up to, but not greater than 10 mg per day, or 20 milligrams every other day are acceptable) despite individual's compliance with tolerated maximum therapy for a period of at least three consecutive months. This is demonstrated by the individual having two or more

exacerbations in the preceding 12 months which is demonstrated by any of the following:
  - For individuals taking inhaled corticosteroids and long-acting beta agonists: asthma symptoms required oral systemic corticosteroids
  - Unscheduled professional provider's office visit due to asthma symptoms
  - Emergency department visit due to asthma symptoms
  - Hospitalization due to asthma symptoms
- Either not a candidate (e.g., non-allergic phenotype, normal IgE levels, cannot tolerate side effects or allergy) or is refractory to a trial of anti-IgE therapy or anti-Interleukin (Il)-5 therapy
- Age 18 years or older
- Non-smoker for one year or greater
  - If former smoker, less than ten pack years total smoking history

Repeat procedures of bronchial thermoplasty beyond the initial three treatment sessions is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Bronchial thermoplasty is considered **not medically necessary** for any of the following contraindications:

- Pacemaker, internal defibrillator, or other implantable electronic devices
- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines
- Same area(s) previously treated with bronchial thermoplasty
- Any of the following conditions present:
  - Active respiratory infection
  - Asthma exacerbation or changing doses of systemic corticosteroids for asthma (up or down) in the past 14 days
  - Known coagulopathy

All other uses for bronchial thermoplasty are considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

NA

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II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.127, Bronchial Thermoplasty. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

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

Asthma

Asthma, a chronic lung disease, affects approximately 8.3% of adults and 8.3% of children in the United States and, in 2017, accounted for approximately 1.7 million emergency department visits and 3615 deaths. 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 postbronchodilator, 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 has defined 6 pharmacologic steps: step 1 for intermittent asthma and steps 2 through 6 for persistent asthma. The preferred daily medications: step 1: short-acting β-agonists as needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting β-agonists (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. Bronchial thermoplasty is intended as a supplemental treatment for patients with severe persistent asthma (i.e., steps 5 and 6 in the stepwise approach to care).

Bronchial thermoplasty procedures are performed on an outpatient basis, and each session lasts approximately 1 hour. During the procedure, a standard flexible bronchoscope is placed through the patient's mouth or nose into the most distal targeted airway and a catheter is inserted into the working channel of the bronchoscope. After placement, the electrode array in the top of the catheter is expanded, and radiofrequency energy is delivered from a proprietary controller and used to heat tissue to 65°C over a 5-mm area. The positioning of the catheter and application of thermal energy is repeated several times in contiguous areas along the accessible length of the airway. At the end of the treatment session, the catheter and bronchoscope are removed. A course of treatment consists of 3 separate procedures in different regions of the lung scheduled about 3 weeks apart.

Regulatory Status

In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, now Boston Scientific) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P080032) for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with low-dose inhaled corticosteroids and long-acting β-agonists. Use of the treatment is contraindicated in patients with implantable devices and those with sensitivities to lidocaine, atropine, or benzodiazepines. It should also not be used while patients are experiencing an asthma exacerbation, active respiratory infection, bleeding disorder, or within 2 weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty. FDA product code: OOY.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty, the evidence includes 3 randomized controlled trials (RCTs) and observational studies. Relevant outcomes are symptoms, quality of life, 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 a 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 United States. Over 1 year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome of mean change in quality of life score, but was found to be superior on a related outcome, improvement in quality of life 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, which suggests a large placebo effect, particularly for subjective outcomes such as quality of life. 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 5 years have been reported in the RCTs for the 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 (i.e., 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 (1 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. In addition, 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.

V. DEFINITIONS

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PREMARKET APPROVAL (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member’s health benefit plan for information or contact Capital BlueCross for benefit information.

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VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary for bronchial thermoplasty when criteria met for initial treatment.

CPT Codes®							
31660	31661						

ICD-10-CM Diagnosis Codes	Description
J45.50	Severe persistent asthma, uncomplicated

IX. REFERENCES

TOP

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2. *National Heart Lung and Blood Institute. Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2007; https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma Accessed June 8, 2020.*
3. *Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Bronchial thermoplasty for treatment of inadequately controlled severe asthma. TEC Assessments. 2014;Volume 29:Tab 12. PMID 25962190*

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16. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. Feb 2014;43(2):343-373. PMID 24337046

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 June 8, 2020.

18. National Institute for Health and Care Excellence (NICE). Bronchial thermoplasty for severe asthma [IPG419]. 2012; https://www.nice.org.uk/guidance/IPG419

Accessed June 8, 2020.

19. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.127. Bronchial Thermoplasty. June 2019.*

X. POLICY HISTORY

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MP-2.081	**CAC 4/26/11** New Policy, Adopt BCBSA. Bronchial thermoplasty is considered "investigational" due to absence of long-term effectiveness and safety outcomes.
	CAC 6/26/12 Consensus review. No changes, references updated. **7/9/12**- FEP variation revised to refer to the FEP medical policy manual.
	New Codes added 12/20/12
	CAC 9/24/13 Consensus review. No changes to policy statements; references updated. Administrative code review complete.
	1/2/14 Administrative update. Rationale added.
	CAC 9/30/14 Minor review considering recent literature. No change to policy statements. Remains investigational. Rationale and references updated.
	CAC 9/29/15 Consensus review. No change to policy statements. References and rational updated. Coding reviewed.
	CAC 7/26/16 Consensus review. No change to policy statements. References and rationale updated. Coding updated.
	11/23/16 Administrative update. Variation reformatting.
	CAC 9/26/17 Consensus review. Policy statement unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	6/7/18 Consensus review. No change to policy statements. References updated. Rationale condensed.
	8/6/18 Minor review. Changed from investigational to medically necessary with criteria. Reviewed rationale and references. Coding updated. Effective 3/1/19.
	7/15/19 Consensus review. No changes to policy statements, rationale and references verified.
	6/2/20 Consensus review. No change to policy statement. Rationale and references reviewed.

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