MEDICAL POLICY

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

Original Issue Date (Created):	**9/1/2011**
Most Recent Review Date (Revised):	**6/7/2018**
Effective Date:	**8/1/2018**

I. POLICY

Bronchial thermoplasty for the treatment of asthma is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
NA

II. PRODUCT VARIATIONS

TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated 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

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

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..[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 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.[2] 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.

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

Regulatory Status
In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, Sunnyvale, CA, now part of 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

TOP

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 3 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 3 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

TOP

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

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross 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. 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

TOP

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.

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

The following code is investigational when used to report bronchial thermoplasty for the treatment of asthma; therefore not covered:

CPT Codes®								
31660	31661							

IX. REFERENCES

TOP

1. *Centers for Disease Control & Prevention, National Center for Health Statistics. Asthma. 2017;*https://www.cdc.gov/nchs/fastats/asthma.htm *Accessed June 7, 2018.*
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 7, 2018.*
3. *Blue Cross Blue Shield AsssociationTechnology Evaluation Center (TEC). Bronchial thermoplasty for treatment of inadequately controlled severe asthma. TEC Assessments. 2014;Volume 29:Tab 12. PMID 25962190*
4. *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):1185-1191. PMID 17901415*
5. *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):402-407. PMID 24125149*
6. *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):1327-1337. PMID 17392302*
7. *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 2011;11:8. PMID 21314924*
8. *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):116-124. PMID 19815809*
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):1295-1302. PMID 23998657*
11. *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*
12. *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*

13. *Langton D, Sha J, Ing A, et al. Bronchial thermoplasty: activations predict response. Respir Res. Jul 4 2017;18(1):134. PMID 28676053*
14. *d'Hooghe JNS, van den Berk IAH, Annema JT, et al. Acute radiological abnormalities after bronchial thermoplasty: a prospective cohort trial. Respiration. Jul 2017;94(3):258-262. PMID 28675890*
15. *Global Initiative for Asthma. Global Initiative for Asthma Management and Prevention. GINA; 2018.*
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 7, 2018.*
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 7, 2018.*
19 *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.127. Bronchial Thermoplasty. June 2018.*

X. POLICY HISTORY

TOP

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.
	Admin posting 1/2/14. 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.
	Administrative Update 11/23/16 Variation reformatting.
	CAC 9/26/17 Consensus review. Policy statement unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP- 2.081

	6/7/18 Consensus. No change to policy statements. References updated. Rationale condensed.

Top