MEDICAL POLICY

POLICY TITLE	BRONCHIAL THERMOPLASTY
POLICY NUMBER	MP 2.081

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

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:

- Presence of a 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.

Policy Guidelines

Bronchial thermoplasty should be performed by clinicians who are experienced in bronchoscopy and have completed the bronchial thermoplasty training curriculum.

Cross-reference:

NA

II. PRODUCT VARIATIONS TOP

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

FEP PPO - Refer to FEP Medical Policy Manual. 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 8.0% of adults and 6.5% 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 2020 and 2021, asthma exacerbations accounted for approximately 1.2 million emergency department visits and 3517 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 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. 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. 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

Several professional societies support the use of bronchial thermoplasty for a select subset of patients. All repeat procedures, beyond the initial 3 treatments are considered experimental,

investigational or unproven due to the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

Per NICE, current evidence on the safety and efficacy of bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit. The procedure should only be done by a multidisciplinary team in specialist centres with on-site access to intensive care. It should only be done by clinicians with training in the procedure and experience in managing severe asthma.

American College of Chest Physicians (ACCP)

ACCP provided a document in May 2014 on the coverage and payment for bronchial thermoplasty for severe persistent asthma. “CHEST believes that based on the strength of the clinical evidence, bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental.”

In 2021, the CHEST journal published “Bronchial Thermoplasty in Patients With Severe Asthma at 5 Years; The Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma Study.” The study concludes that “Five years after treatment, subjects experienced decreases in severe exacerbations, hospitalizations, ED visits, and corticosteroid exposure. All subgroups demonstrated clinically significant improvement, suggesting that bronchial thermoplasty improves asthma control in different asthma phenotypes.”

Global Initiative for Asthma (GINA)

In the Global Strategy for Asthma and Management and Prevention (updated 2020) mentions “bronchial thermoplasty is a potential treatment option at Step 5 for adult patients whose asthma remains uncontrolled despite optimized therapeutic regimens and referral to an asthma specialty center. (Evidence B)” The 2020 report also advises that “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 in order to accumulate further evidence about effectiveness and safety of the procedure.”

American College of Allergy, Asthma, and Immunology (ACAAI)

January 1, 2015 ACAAI made a statement on bronchial thermoplasty: “Bronchial thermoplasty is a well-studied treatment for patients with very severe asthma who continue to be symptomatic despite maximal medical treatment including steroids, long-acting beta agonists

(LABAs), long-acting muscarinic agents (LAMAs), leukotriene antagonists and biologics. The device to deliver this therapy is FDA approved.

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.

Therefore, ACAAI recommends that insurers provide coverage for bronchial thermoplasty for those adult patients who meet the stringent requirements."

National Asthma Education and Prevention Program
In 2020, the National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) Expert Panel Working Group published focused updates to the National Heart, Lung, and Blood Institute's guidelines for the diagnosis and management of asthma. This update was based on prior systematic reviews of the evidence published by the Agency for Healthcare Research and Quality.

The following conditional recommendation based on low certainty evidence on the use of bronchial thermoplasty was issued:

- "In individuals ages 18 years and older with persistent asthma, the Expert Panel conditionally recommends against bronchial thermoplasty.
- Individuals ages 18 years and older with persistent asthma who place a low value on harms (short-term worsening symptoms and unknown long term side effects) and a high value on potential benefits (improvement in quality of life, a small reduction in exacerbations) might consider bronchial thermoplasty."

For patients who opt to choose this intervention via shared decision-making, the panel recommends that clinicians offer the procedure in the setting of a clinical trial or registry study to facilitate the collection of long-term outcomes.

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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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.

Procedure Codes							
31660	31661						

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

IX. REFERENCES

TOP

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X. POLICY HISTORY

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MP-2.081	**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.
	10/26/2021 Consensus review. Rationale, policy guidelines and references updated. Addition of society guidelines in rationale.
	12/9/2022 Consensus review. No changes to policy statement. Updated background, references. No coding changes.
	8/15/2023 Consensus review. No changes to policy statement. Updated background, rationale, references. No coding changes.
	1/18/2024 Administrative review. Clinical benefit added.

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