Clinical Policy: Bronchial Thermoplasty

Reference Number: IL.CP.MP.506 Coding Implications
Last Review Date: 03/22 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Bronchial Thermoplasty:	A catheter based treatment for severe asthma approved by the FDA in 2010 involving the delivery of controlled, therapeutic radiofrequency energy to the airway wall through a bronchoscope, heating the tissue and reducing the amount of smooth muscle present in the airway wall, thus decreasing bronchoconstriction.

Asthma is a chronic lung disease that causes inflammation and narrowing of the airway, causing recurring periods of wheezing, chest tightness, shortness of breath and coughing. Standard treatment approaches for asthma involve environmental control measures and avoidance of risk factors, plus comprehensive drug therapy. Long-term control medications, such as inhaled corticosteroids or long-acting beta2-agonists, help reduce airway inflammation and prevent asthma symptoms. Quick-relief medications, such as short-acting beta2-agonists, relieve asthma symptoms that may flare up.

In addition to ongoing efforts to optimally implement standard approaches to the treatment of asthma, new therapies are being developed. One new 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 by means of 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 despite optimal management with current care medication regimens (i.e., steps 5 and 6 in the stepwise approach to care as identified below).

Policy/Criteria

I. It is the policy of MeridianHealth affiliated with Centene Corporation® that bronchial thermoplasty is considered **experimental or investigational**.

II. Bronchial Thermoplasty (BT) for the treatment of asthma and other conditions (chronic obstructive pulmonary disease) is considered **experimental or investigational** due to insufficient clinical evidence published in the peer-reviewed literature regarding safety and longterm efficacy of this technology. Due to the fact that BT is currently considered experimental and investigational it is not a covered benefit. There is insufficient and low quality evidence regarding the use of bronchial thermoplasty in patients with severe asthma, who are resistant to standard therapies. The presence of substantial adverse

events leaves a large degree of uncertainty about the impact of bronchial thermoplasty on the net health outcome. There is also a lack of conclusive evidence confirming long term efficacy and safety as well as a lack of data on patient selection factors for this procedure. As a result, it is not possible to determine which patient's receive the most benefit.

III. Asthma is a chronic lung disease that causes inflammation and narrowing of the airway, causing recurring periods of wheezing, chest tightness, shortness of breath and coughing. Standard treatment approaches for asthma involve environmental control measures and avoidance of risk factors, plus comprehensive drug therapy. Long-term control medications, such as inhaled corticosteroids or long-acting beta2-agonists, help reduce airway inflammation and prevent asthma symptoms. Quick-relief medications, such as short-acting beta2-agonists, relieve asthma symptoms that may flare up.

IV. In addition to ongoing efforts to optimally implement standard approaches to the treatment of asthma, new therapies are being developed. One new 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 by means of 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 despite optimal management with current care medication regimens (i.e., steps 5 and 6 in the stepwise approach to care as identified below).

V. **Stepwise Approach to Care:** Guidelines from the National Heart, Lung and Blood Institute (NHLBI) define 6 pharmacologic steps for the treatment of asthma (step 1 for intermittent asthma, and steps 2 – 6 for persistent asthma). The preferred daily medications include the following:

A. Step 1: Short-acting beta-agonists as needed;
B. Step 2: Low-dose inhaled corticosteroids (ICS);
C. Step 3: ICS and long-acting beta-agonists (LABA) or medium-dose ICS;
D. Step 4: Medium dose ICS and LABA;
E. Step 5: High-dose ICS and LABA;
F. Step 6: High-dose ICS and LABA, and oral corticosteroids.

VI. **European Respiratory Society/American Thoracic Society definition of severe Asthma for patients ages ≥ 6 years***

The definition of severe asthma requires that one or both of the following levels of treatment for the previous year has been needed to prevent asthma from becoming uncontrolled or asthma that remains uncontrolled despite this level of treatment:
• Treatment with guidelines suggested medications for GINA (Global Initiative for Asthma steps 4-5 asthma (high dose inhaled glucocorticoid and long-acting beta agonist [LABA] or leukotriene modifier/theophylline) for the previous year
• Treatment with systemic glucocorticoid for ≥50% of the year
Uncontrolled asthma is defined as at least one of the following:

• Poor symptom control: ACQ (asthma control questionnaire) consistently >1.5, ACT (asthma control test) <20 (or "not well controlled" by NAEPP (National Asthma Education Prevention Program)/GINA guidelines)
• Frequent severe exacerbations: two or more bursts of systemic glucocorticoids (more than three days each) in the previous year
• History of serious exacerbation: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year
• Airflow limitation: after appropriate bronchodilator withhold FEV_1 <80% predicted (in the face of reduced FEV_1/FVC defined as less than the lower limit of normal)

** European Respiratory Society: Eur Respir J February 2014 43:343-373*

Background

Bronchial thermoplasty (BT) is a minimally invasive technique that has been proposed to treat patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta2 agonists. A Cochrane review by Torrego et al. (2014) concluded that BT for patients with moderate to severe asthma provides a modest clinical benefit in quality of life and lower rates of asthma exacerbation, but no significant difference in asthma control scores. The quality of life findings are at risk of bias, as the main benefits were seen in the two studies that did not include a sham treatment arm. This procedure increases the risk of adverse events during treatment but has a reasonable safety profile after completion of the bronchoscopies. The overall quality of evidence regarding this procedure is moderate. For clinical practice, it would be advisable to collect data from patients systematically in independent clinical registries

The overall body of evidence concerning bronchial thermoplasty for treatment of asthma was small in size and low in quality. The evidence comprised 1 good-quality RCT, 2 fair-quality RCTs, 1 very-poor-quality retrospective cohort study, and 3 very-poor-quality case series. The body of evidence was considered to be of low quality, primarily because of inconsistent results regarding short-term benefits of bronchial thermoplasty, varied patient selection criteria across studies, poor quality (i.e., a high risk of bias) of several of the individual studies, a small quantity of RCTs available, small sample sizes in most of the reviewed studies, and insufficient evidence concerning the long-term efficacy of bronchial thermoplasty (Hayes, 2016).

A National Institute for Health and Care Excellence (NICE) guidance document states that the 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. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2012).

European Respiratory Society (ERS) / American Thoracic Society (ATS): Guidelines prepared jointly strongly recommend that bronchial thermoplasty be performed only in adults with severe asthma and only in the context of a clinical trial or independent systematic registry.

The Global Initiative for Asthma (GINA) 2017 update states "Due to the risk of the procedure and modest degree of improvement, additional data are needed regarding long-term effects and morphologic changes in the airways in order to determine the ideal role for BT in asthma. Thus, for patients who meet criteria for BT, we advise undergoing BT in the context of a clinical trial or registry.

There are several ongoing studies regarding the safety and efficacy of Bronchial Thermoplasty which are hoped to provide more long term, quality evidence.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		3/27/15
Annual review - policy will be retired		03/2022

References

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12. Global Strategy for Asthma Management and Prevention, 2016. Updated March 2018
13. International ERS/ATS Guidelines on Definition, evaluation and treatment of severe asthma, 2014
14. UptoDate “Treatment of Severe Asthma in Adults”. December, 2018
15. State of Illinois Contract between the Department of Healthcare and Family Services and Meridian Health Plan of Illinois, 2018-24-601, Preauthorization and Concurrent Review Requirements, 1.1.2.3.3

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.