Clinical Policy: Bronchial Thermoplasty

Reference Number: CP.MP.110
Last Review Date: 03/19

Coding Implications
Revision Log

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

Description

This policy describes the medical necessity requirements for bronchial thermoplasty (BT). BT is a bronchoscopic procedure that utilizes radiofrequency ablation to reduce airway smooth muscle cells. It is designed to serve as a therapeutic option to reduce severe bronchoconstriction for severe persistent asthma.

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that bronchial thermoplasty is **not medically necessary** for severe asthma because its long-term safety and effectiveness has not been proven.

Background

Asthma is a common inflammatory syndrome caused by chronic, intermittent obstruction of the lower respiratory tract that affects millions of individuals. This process is mediated by several inflammatory cytokines, chemokines, adhesion molecules, and signal transduction cascades.[1] T helper type 2 (T_H2) and type 17 (T_H17) $CD4^+$, basophils, eosinophils, mast cells, and type 2 innate lymphoid cells are crucial for mediating the asthmatic response.[2]

BT is a bronchoscopic procedure that applies thermal energy to the airway wall and, thereby, reduces the extent of airway smooth muscle cell hypertrophy via radiofrequency ablation.[3] Some studies published on BT have tested its therapeutic potential against severe asthma.[4] However, the literature recently published on BT has been controversial and the studies evaluating the efficacy of BT have not provided consistent results.

A prospective non-randomized study of 16 patients with stable mild to moderate asthma found a significant reduction in airway hyperresponsiveness without a change in FEV_1.[5] The Asthma Intervention Research Trial (AIR), a randomized controlled trial that enrolled 112 patients, showed an improvement in asthma symptoms from BT but no reduction in hyperresponsiveness or FEV_1.[6] The Research in Severe Asthma Trial (RISA), a small randomized study that enrolled only 32 patients, assessed the safety of BT in patients receiving high doses of steroids. Despite several complications, including hospitalizations, a difference was seen in the BT group versus control.[7] Some critics argue that these studies lack the statistical power and blinded placebo control to demonstrate clear conclusions on the efficacy of BT's clinical potential.[8]

In 2010, Castro *et al*. performed a randomized, controlled trial with 288 patients that included a placebo control. This study was called the Asthma Intervention Research Trial 2 (AIR2).[9] AIR2 found a statistically significant improvement in their primary outcome, which was the score from the Asthma Quality of Life Questionnaire (AQLQ).[9] However, these scores fell below a clinically meaningful threshold.[4] There was no difference in peak flow, rescue medication use, or FEV_1.[9] Moreover, several investigators have criticized the AIR2 study for failing to meet

secondary outcome measures such as safety, its patient selection, and its true efficacy.[8,10,11] Thus, this study also remains controversial.

Hayes conducted a review of the available literature on BT, noting that overall the body of evidence is small and of low quality. The findings were that BT may improve quality of life outcomes, however other results including emergency department visits, symptom relief, and medication use were inconsistent across studies. BT was found to not decrease hospitalization following treatment and it actually increased hospitalization during the treatment period. Treatment with BT was associated with a statistically significant increase in complications such as wheezing, chest discomfort, night awakenings, sputum discoloration, and cough. The quality and quantity of evidence was not enough to establish the long-term safety and efficacy of the procedure.[12]

Lastly, a meta-analysis of the aforementioned randomized, controlled trials by Wu, et al, suggests that while BT significantly improves AQLQ scores, there were more respiratory adverse events and hospitalizations for respiratory adverse events with BT than with medications or with placebo.[13]

European Respiratory Society/American Thoracic Society
A 2014 joint statement by the European Respiratory Society and American Thoracic Society strongly recommends that BT be performed only in adults with severe asthma, in the context of a clinical trial or independent systematic registry. They conclude that the body of evidence is of very low quality, and that long-term benefits and safety are unknown.

National Institute for Health and Care Excellence (NICE)
NICE guidance states that current evidence on the safety and efficacy of BT 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. BT should only be done by clinicians with training in the procedure and experience in managing severe asthma. Further research should report details of patient selection and long-term safety and efficacy outcomes.

Global Initiative for Asthma
The Global Initiative for Asthma recommends BT as a potential option for highly selected adult patients who have uncontrolled asthma despite use of recommended therapeutic regimens and referral to an asthma specialty center. Evidence is limited and long-term effects compared with control patients are unknown.

Coding Implications
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CPT® Codes	Description
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

ICD-10-CM Diagnosis Codes

ICD-10-CM Code	Description
J45.20-J45.998	Asthma

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	04/16	05/16
References reviewed and updated.	04/17	05/17
Background information from ETS/ATS, NICE, and GINA added. References reviewed and updated.	03/18	03/18
Background information from NICE updated. Specialist reviewed. References reviewed and updated	03/19	03/19

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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.

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Note: For Medicare members, 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.