# Clinical Policy: Bronchial Thermoplasty

Reference Number: CP.MP.110
Date of Last Revision: 05/22

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 the long-term safety and effectiveness of bronchial thermoplasty has not been proven for severe asthma or any other indications.

**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]

Bronchial thermoplasty (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, recent literature 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.

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.[12]

Studies at 5 year follow up have reported BT to be safe (stable pulmonary function test and no bronchiectasis on chest CT) with persistent reductions in asthma exacerbation rates and/or emergency department visits/hospitalizations.[20-21] The complexity and uncertainties in the selection of patients for BT require a multidisciplinary team approach at asthma centers with high volumes of severe asthma patients and a high level of experience in interventional pulmonology procedures.[20]

*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.[14]

*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.[15]

*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. Caution should be used in selecting patients for this procedure. BT 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, so that further evidence about effectiveness and safety of the procedure can be accumulated. Longer-term follow-up of larger cohorts comparing effectiveness and safety, including lung function, in both active and sham- treated patients is needed.[16]

*Agency for Healthcare Research and Quality*
Three RCTs and several descriptive studies meeting our inclusion criteria have evaluated BT. Based on the available literature, BT may be modestly beneficial in some patients with asthma, but is not without risks in any population. The risk of adverse events is higher during the treatment period and for several weeks afterward. Benefit is typically observed weeks to months after therapy and can last for at least 5 years, after which the duration of effect is unknown.[18]

*British Thoracic Society*

Further research is needed to identify which patients with asthma might benefit from BT. However, it is likely that patients who remain uncontrolled despite optimal medical treatment and who have been considered for biological treatments and are either unsuitable for or fail a trial of such a treatment may be an appropriate group, as other treatment options for these patients are elusive. There are no trials comparing the efficacy of BT with biological treatments for people with asthma. BT may be considered for the treatment of adult patients (aged 18 and over) with severe asthma who have poorly-controlled asthma despite optimal medical therapy**.** An asthma specialist with expertise in BT should assess patients prior to undergoing treatment, and treatment should take place in a specialist centre with the appropriate resources and training, including access to an intensive care unit.[19]

**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 |

| Reviews, Revisions, and Approvals | Revision 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 |
| Revised policy statement to investigational rather than not medically necessary. Background updated. References reviewed and updated. | 02/20 | 04/20 |
| "Experimental/investigational" verbiage replaced in policy statement with descriptive language." Removed ICD-10 table. Replaced all instances of "members" with "members/enrollees". References reviewed and updated. | 04/21 | 04/21 |
| Annual review. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date. Background updated with no impact to criteria. References reviewed and updated. Coding verified. | 05/22 | 05/22 |

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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 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.