

# Clinical Policy: Bronchial Thermoplasty

Reference Number: PA.CP.MP.110

Last Review Date: 07/30/2021

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Coding Implications

Revision Log

## 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 PA Health & Wellness (PHW)<sup>®</sup> that the long-term safety and effectiveness of bronchial thermoplasty has not been proven for severe asthma or any other indications. PA Medical Assistance would consider bronchial thermoplasty on a case by case basis.

## 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.<sup>1</sup> T helper type 2 (T<sub>H</sub>2) and type 17 (T<sub>H</sub>17) CD4<sup>+</sup>, basophils, eosinophils, mast cells, and type 2 innate lymphoid cells are crucial for mediating the asthmatic response.<sup>2</sup>

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.<sup>3</sup> Some studies published on BT have tested its therapeutic potential against severe asthma.<sup>4</sup> 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 hyper-responsiveness without a change in FEV<sub>1</sub>.<sup>5</sup> 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 hyper-responsiveness or FEV<sub>1</sub>.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup>

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).<sup>9</sup> AIR2 found a statistically significant improvement in their primary outcome, which was the score from the Asthma Quality of Life Questionnaire (AQLQ).<sup>9</sup> However, these scores fell below a clinically meaningful threshold.<sup>4</sup> There was no difference in peak flow, rescue medication use, or FEV<sub>1</sub>.<sup>9</sup> 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.<sup>8,10,11</sup> 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.<sup>12</sup>

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.<sup>13</sup>

*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 |

| 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. Revised policy statement to investigational rather than not medically necessary. Specialist reviewed. References reviewed and updated.                                      | 08/2020 | 8/2020        |
| “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. | 7/2021  | 9/7/2021      |

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