

## Clinical Policy: Bronchial Thermoplasty

Reference Number: PA.CP.MP.110

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### 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.<sup>1</sup> It is designed to serve as a therapeutic option to reduce severe bronchoconstriction for severe persistent asthma.<sup>1</sup>

### Policy/Criteria

- I. It is the policy of PA Health & Wellness<sup>®</sup> 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.<sup>2</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>3</sup>

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.<sup>1</sup> Some studies published on BT have tested its therapeutic potential against severe asthma.<sup>4</sup> 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 no change in forced expiratory volume in the first second (FEV<sub>1</sub>) but found a significant reduction in airway hyperresponsiveness.<sup>5</sup> The Asthma Intervention Research Trial (AIR), a randomized controlled trial (RCT) that enrolled 112 patients, showed an improvement in asthma symptoms from BT but no reduction in FEV<sub>1</sub> or hyperresponsiveness.<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, FEV<sub>1</sub>, or rescue medication use.<sup>9</sup> Moreover, several investigators have criticized the AIR2 study for failing to meet secondary outcome measures such as safety, patient selection, and its true efficacy.<sup>8,10,11</sup> 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.<sup>12</sup>

Studies at five 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.<sup>13,14,15</sup> 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.<sup>13</sup>

The BT10+ study aimed to research the safety and efficacy of BT after 10 or more years and included 192 (45%) of the 429 participants who were previously enrolled in AIR, RISA, and AIR2 trials.<sup>16</sup> Of these participants, 136 received BT in the original trials, and 56 of these participants were sham or control participants from the original trials.<sup>16</sup> All participants in the BT10+ study were followed for 10.8 to 15.6 years post-treatment with a median of 12.1 years.<sup>16</sup> Results from the BT10+ study visit were compared with one year and five years after treatment and showed similar proportions of severe exacerbations, quality of life measurements, and spirometry.<sup>16,17</sup> Reductions in severe exacerbations were also seen at the BT10+ study visit compared with baseline in participants who were treated with BT after the original study and participants in the sham or control group.<sup>16</sup> The BT10+ study findings suggest that BT is sustained with an acceptable safety profile for 10 or more years.<sup>16</sup> However, the loss to follow-up and differences between trials limit the conclusions that can be made based on this study.<sup>17</sup>

According to Hayes, which includes evaluation of the BT10+ study, there is a low-quality body of evidence for the use of BT in patients with severe asthma. Studies did show improvement in symptom control and quality of life after BT treatment compared to baseline values, however, there were inconsistencies in outcomes among several studies. Hayes suggests that additional studies should investigate which patients with severe asthma would benefit the most from BT, and further evaluation should be made regarding the efficacy of BT compared with other add-on treatments for severe persistent asthma.<sup>18</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.<sup>19</sup>

#### *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. NICE guidance also states that further research should report additional information regarding patient selection and long-term safety and efficacy of outcomes.<sup>20</sup>

*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. In order to obtain additional evidence for efficacy and safety, BT should only be performed in adults with severe asthma in the context of an independent Institutional Review Board-approved systematic registry or a clinical study. Additional, long-term follow-up of larger cohorts in both active and sham treated patients is needed to compare effectiveness and safety.<sup>21</sup>

*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 center with the appropriate resources and training, including access to an intensive care unit.<sup>22</sup>

**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.                              | 08/2020       | 08/2020       |

| Reviews, Revisions, and Approvals   | Revision Date | Approval Date |
|---|---------------|---------------|
| References reviewed and updated   |               |               |
| Revised policy statement to investigational rather than not medically necessary. Background updated. References reviewed and updated.   | 08/2020       | 08/2020       |
| “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.                   | 03/23         |               |
| 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. | 03/23         |               |
| Annual Review. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.   | 03/23         |               |
| Annual review. Background updated with no impact on criteria. References reviewed and updated.  | 04/2024       |               |

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