Clinical Policy: Bronchial Thermoplasty
Reference Number: CP.MP.110
Effective Date: 05/16
Last Review Date: 05/17

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. T helper type 2 (T\textsubscript{H}2) and type 17 (T\textsubscript{H}17) CD4\textsuperscript{+}, basophils, eosinophils, mast cells, and type 2 innate lymphoid cells are crucial for mediating the asthmatic response.

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. Some studies published on BT have tested its therapeutic potential against severe asthma. 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\textsubscript{1}. 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\textsubscript{1}. 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. 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.

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). AIR2 found a statistically significant improvement in their primary outcome, which was the score from the Asthma Quality of Life Questionnaire (AQLQ). However, these scores fell below a clinically meaningful threshold. There was no difference in peak flow, rescue medication use,
or FEV₁. 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. 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.

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.

Coding Implications
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<th>Description</th>
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<tr>
<td>31660</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe</td>
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<tr>
<td>31661</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes</td>
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<th>Reviews, Revisions, and Approvals</th>
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<td>Policy developed</td>
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<td>References reviewed and updated.</td>
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References

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.
CLINICAL POLICY
Bronchial Thermoplasty

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Note: For Medicaid members, 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, 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.

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