

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 FEV₁.⁵ 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 FEV₁.⁶ 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 FEV₁.⁹ Moreover, several investigators have criticized the AIR2 study for failing to meet

CLINICAL POLICY

Bronchial Thermoplasty

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

CLINICAL POLICY
Bronchial Thermoplasty

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

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2021, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

References

1. Barnes PJ. Immunology of asthma and chronic obstructive pulmonary disease. *Nat Rev Immunol.* 2008;8(3):183-192. doi:10.1038/nri2254
2. Lambrecht BN, Hammad H. The immunology of asthma. *Nat Immunol.* 2015;16(1):45-56. doi:10.1038/ni.3049
3. Miller JD, Cox G, Vincic L, Lombard CM, Loomas BE, Danek CJ. A prospective feasibility study of bronchial thermoplasty in the human airway. *Chest.* 2005;127(6):1999-2006. doi:10.1378/chest.127.6.1999
4. Wahidi MM, Kraft M. Bronchial thermoplasty for severe asthma. *Am J Respir Crit Care Med.* 2012;185(7):709-714. doi:10.1164/rccm.201105-0883CI
5. Cox G, Miller JD, McWilliams A, Fitzgerald JM, Lam S. Bronchial thermoplasty for asthma. *Am J Respir Crit Care Med.* 2006;173(9):965-969. doi:10.1164/rccm.200507-1162OC
6. Cox G, Thomson NC, Rubin AS, et al. Asthma control during the year after bronchial thermoplasty. *N Engl J Med.* 2007;356(13):1327-1337. doi:10.1056/NEJMoa064707
7. Pavord ID, Cox G, Thomson NC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med.* 2007;176(12):1185-1191. doi:10.1164/rccm.200704-571OC
8. Bel EH. Bronchial thermoplasty: has the promise been met?. *Am J Respir Crit Care Med.* 2010;181(2):101-102. doi:10.1164/rccm.200910-1616ED
9. Castro M, Rubin AS, Laviolette M, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. *Am J Respir Crit Care Med.* 2010;181(2):116-124. doi:10.1164/rccm.200903-0354OC
10. Laxmanan B, Egressy K, Murgu SD, White SR, Hogarth DK. Advances in Bronchial Thermoplasty. *Chest.* 2016;150(3):694-704. doi:10.1016/j.chest.2016.03.012
11. Iyer VN, Lim KG. Bronchial thermoplasty: Where there is smoke, there is fire. *Allergy Asthma Proc.* 2015;36(4):251-255. doi:10.2500/aap.2015.36.3857
12. Wu Q, Xing Y, Zhou X, Wang D. Meta-analysis of the efficacy and safety of bronchial thermoplasty in patients with moderate-to-severe persistent asthma. *J Int Med Res.* 2011;39(1):10-22. doi:10.1177/147323001103900102
13. O'Reilly A, Browne I, Watchorn D, Egan JJ, Lane S. The efficacy and safety of bronchial thermoplasty in severe persistent asthma on extended follow-up. *QJM.* 2018;111(3):155-159. doi:10.1093/qjmed/hcx221
14. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma [published correction appears in *Eur Respir J.* 2014 Apr;43(4):1216. Dosage error in article text] [published correction appears in *Eur Respir J.* 2018 Jul 27;52(1):]. *Eur Respir J.* 2014;43(2):343-373. doi:10.1183/09031936.00202013
15. Bronchial thermoplasty for severe asthma - Interventional procedures guidance IPG635. National Institute for Health and Care Excellence. <https://www.nice.org>. Published December 19, 2018. Accessed May 6, 2022.
16. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. <https://ginasthma.org/>. Published 2022. Accessed May 6, 2022.
17. Wenzel S. Treatment of severe asthma in adolescents and adults. UpToDate. www.uptodate.com. Published March 23, 2022. Accessed May 6, 2022.

CLINICAL POLICY

Bronchial Thermoplasty

18. Effectiveness and safety of bronchial thermoplasty in management of asthma – number 202. Agency for Healthcare Research and Quality. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-202-thermoplasty-final_0.pdf. Published December 2017. Accessed May 6, 2022.
19. British guideline on the management of asthma – sign 158. British Thoracic Society. <https://www.sign.ac.uk/media/1773/sign158-updated.pdf>. Published 2003 (revised July 2019). Accessed May 6, 2022.
20. Bonta PI, Chanez P, Annema JT, Shah PL, Niven R. Bronchial Thermoplasty in Severe Asthma: Best Practice Recommendations from an Expert Panel. *Respiration*. 2018;95(5):289-300. doi:10.1159/000488291
21. Zhou JP, Feng Y, Wang Q, Zhou LN, Wan HY, Li QY. Long-term efficacy and safety of bronchial thermoplasty in patients with moderate-to-severe persistent asthma: a systemic review and meta-analysis. *J Asthma*. 2016;53(1):94-100. doi:10.3109/02770903.2015.1065424

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

CLINICAL POLICY

Bronchial Thermoplasty

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.