Clinical Policy: Bronchial Thermoplasty

Reference Number: WNC.CP.176
Last Review Date: 04/23

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Note: 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.

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.[1] It is designed to serve as a therapeutic option to reduce severe bronchoconstriction for severe persistent asthma.[1]

Policy/Criteria

I. It is the policy of WellCare of North Carolina® 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.[2] 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.[3]

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.[1] 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 no change in forced expiratory volume in the first second (FEV_1) but found a significant reduction in airway hyperresponsiveness.[5] 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 FEV1 or hyperresponsiveness. [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, FEV_1, or rescue medication use.[9] Moreover, several investigators have criticized the AIR2 study for failing to meet secondary outcome measures such as safety, 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.[13-15] 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.[13]

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.[16] One hundred thirty six of these participants received BT in the original trials, and 56 of these participants were sham or control participants from the original trials.[16] All participants in the BT10+ study were followed for 10.8 to 15.6 years post-treatment with a median of 12.1 years.[16] 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.[16,17] 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.[16] The BT10+ study findings suggest that BT is sustained with an acceptable safety profile for 10 or more years.[16] However, the loss to follow-up and differences between trials limit the conclusions that can made based on this study.[17]

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.[18]

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.[19]

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.[20]

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.[21]

Agency for Healthcare Research and Quality
Results from three randomized controlled trials and several descriptive studies evaluating BT led the Agency for Healthcare Research and Quality to conclude that 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.[22]

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.[23]

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 2022, 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	Reviewed Date	Approval Date
Original approval date	03/21	05/21
Additional descriptive language added to Criteria. ICD-10 table removed. References reviewed and updated.	07/21	08/21
Background updated with no impact to criteria. References reviewed and updated. Coding verified.	06/22	08/22
Annual Review. NCHC verbiage removed from NC Guidance Verbiage. Background updated with no impact on criteria. References reviewed and updated.	04/23	

References

1. 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 to 2006. doi:10.1378/chest.127.6.1999
2. Barnes PJ. Immunology of asthma and chronic obstructive pulmonary disease. *Nat Rev Immunol*. 2008;8(3):183 to 192. doi:10.1038/nri2254
3. Lambrecht BN, Hammad H. The immunology of asthma. *Nat Immunol*. 2015;16(1):45 to 56. doi:10.1038/ni.3049
4. Wahidi MM, Kraft M. Bronchial thermoplasty for severe asthma. *Am J Respir Crit Care Med*. 2012;185(7):709 to 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 to 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 to 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 to 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 to 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 to 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 to 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 to 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 to 22. doi:10.1177/147323001103900102
13. 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 to 300. doi:10.1159/000488291
14. 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 to 100. doi:10.3109/02770903.2015.1065424
15. 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 to 159. doi:10.1093/qjmed
16. Chaudhuri R, Rubin A, Sumino K, et al. Safety and effectiveness of bronchial thermoplasty after 10 years in patients with persistent asthma (BT10+): a follow-up of three randomised controlled trials. *Lancet Respir Med*. 2021;9(5):457 to 466. doi:10.1016/S2213-2600(20)30408-2
17. Wenzel S. Treatment of severe asthma in adolescents and adults. UpToDate. www.uptodate.com. Published October 21, 2022. Accessed January 31, 2023.
18. Health Technology Assessment. Bronchial thermoplasty for treatment of asthma in adults. Hayes. www.hayesinc.com. Published July 05, 2022. Accessed February 02, 2023.
19. 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):] [published correction appears in Eur Respir J. 2022 Jun 9;59(6):]. *Eur Respir J*. 2014;43(2):343 to 373. doi:10.1183/09031936.00202013
20. 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 February 13, 2023.
21. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Published 2022. Accessed February 02, 2023.
22. 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 February 13, 2023.
23. British Thoracic Society and Scottish Intercollegiate Guidelines Network. Sign 158 British guideline on the management of asthma.

https://www.sign.ac.uk/media/1773/sign158-updated.pdf. Published 2003 (revised July 2019). Accessed February 01, 2023.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

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 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.

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