



MEDICAL COVERAGE POLICY

SERVICE: Bronchial Thermoplasty

Policy Number: 207

Effective Date: 03/01/2021

Last Review: 01/28/2021

Next Review Date: 01/28/2022

Important note:

Unless otherwise indicated, this policy will apply to all lines of business.

Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Bronchial Thermoplasty

PRIOR AUTHORIZATION: Not applicable.

POLICY: SWHP/FirstCare considers bronchial thermoplasty for the treatment of asthma and other indications (e.g., chronic obstructive pulmonary disease) experimental and investigational because its effectiveness has not been established. Therefore, this is **NOT** a covered procedure.

OVERVIEW:

Asthma is one of the most common chronic diseases in the United States, and its prevalence has been increasing since 1980. In 2000, asthma was responsible for 4,487 deaths, about 0.5 million hospitalizations, 1.8 million visits to the emergency room, and 10.4 million visits to the physician office among individuals of all ages. Approximately 7% of the U.S population has asthma. According to the National Heart, Lung and Blood Institute's (2002) global strategy for asthma management and prevention, the preferred therapy for patients with moderate persistent asthma is regular treatment with a combination of inhaled corticosteroids and a long-acting inhaled beta 2-agonist twice-daily. For patients with severe persistent asthma, the primary therapy includes inhaled corticosteroid at higher doses plus a long-acting inhaled beta 2-agonist twice-daily.

Bronchial thermoplasty is a bronchoscopic procedure that employs radiofrequency ablation to reduce the mass of airway smooth muscle (ASM), thus attenuating bronchoconstriction. It is being studied as a minimally invasive method to improve asthma control. Bronchial thermoplasty is performed on an out-patient basis with conscious sedation (i.e., no general anesthesia is needed), and it usually takes approximately one hour to complete. There are two assumptions that underlie the development of this procedure: (i) ASM is a vestigial tissue; and (ii) treatment directed at ASM alone will provide sustained symptomatic and physiological improvement in patients with asthma. Typically three separate treatments are done over a number of weeks.

Early results have been promising in regards to a reduction in asthma attacks of approximately 50%. However, results have been mixed in sham studies. There are a few studies suggesting safety and efficacy at least until 2 years. However, these studies have largely been industry sponsored and there are no large RCTs.



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The procedure does carry considerable risk. Perforation of a bronchus can lead to a pneumothorax, bronchopleural fistula, or severe mediastinitis infection. These could be morbid or fatal complications.

MANDATES: None

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	31660 - Bronchoscopy with bronchial thermoplasty, 1 lobe 31661 - Bronchoscopy with bronchial thermoplasty, 2+ lobes
ICD10 Not covered	J44.1 Chronic obstructive pulmonary disease with (acute) exacerbation J44.9 Chronic obstructive pulmonary disease, unspecified J45.50 Severe persistent asthma, uncomplicated J45.51 Severe persistent asthma with (acute) exacerbation J45.52 Severe persistent asthma with status asthmaticus J45.9 Other and unspecified asthma J45.90 Unspecified asthma

CMS: No NCD or LCD for this procedure.

POLICY HISTORY:

Status	Date	Action
New	02/14/2013	New policy
Reviewed	02/14/2014	Reviewed. ICD10 codes added.
Reviewed	02/12/2015	No changes
Reviewed	02/04/2016	No changes
Reviewed	01/31/2017	Literature reviewed. No changes
Reviewed	01/23/2018	Literature reviewed. No changes
Reviewed	01/15/2019	No changes
Reviewed	01/23/2020	Literature reviewed. No changes
Reviewed	01/28/2021	No changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP/FirstCare so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Cox PG, Miller J, Mitzner W, Leff AR. Radiofrequency ablation of airway smooth muscle for sustained treatment of asthma: Preliminary investigations. Eur Respir J. 2004;24(4):659-663.
2. Centers for Disease Control and Prevention (CDC). Self-reported asthma prevalence and control among adults--United States, 2001. MMWR Morb Mortal Wkly Rep. 2003;52(17):381-384.



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3. Miller JD, Cox G, Vincic L, et al. A prospective feasibility study of bronchial thermoplasty in the human airway. *Chest*. 2005;127(6):1999-2006.
4. Cox G, Miller JD, McWilliams A, et al. Bronchial thermoplasty for asthma. *Am J Respir Crit Care Med*. 2006;173(9):965-969.
5. Bel EH. 'Hot stuff': Bronchial thermoplasty for asthma. *Am J Respir Crit Care Med*. 2006;173(9):941-942.
6. Mitzner W. Bronchial thermoplasty in asthma. *Allergol Int*. 2006;55(3):225-234.
7. Global Initiative for Asthma (GINA), National Heart, Lung and Blood Institute (NHLBI). Global strategy for asthma management and prevention. Revised 2006. Bethesda, MD: Global Initiative for Asthma (GINA), National Heart, Lung and Blood Institute (NHLBI); 2006. Available at: <http://www.ginasthma.com/Guidelineitem.asp?i1=2&i2=1&intId=60>. Accessed October 8, 2007.
8. Cox G, Thomson NC, Rubin AS, et al; AIR Trial Study Group. Asthma control during the year after bronchial thermoplasty. *N Engl J Med*. 2007;356(13):1327-1337.
9. Solway J, Irvin CG. Airway smooth muscle as a target for asthma therapy. *N Engl J Med*. 2007;356(13):1367-1369.
10. Zamora L. Bronchial thermoplasty for asthma. Horizon Scanning Technology Prioritising Summary. Canberra, ACT: Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S); August 2007.
11. Canadian Agency for Drugs and Technologies in Health (CADTH). Bronchial thermoplasty: A hot approach to asthma treatment? *Health Technol Update*. 2007;6:5.
12. 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.
13. Rubin AS, Cardoso PF. Bronchial thermoplasty: Report on the first endoscopic treatment for asthma in Latin America. *J Bras Pneumol*. 2008;34(1):59-62.
14. Wechsler ME. Bronchial thermoplasty for asthma: A critical review of a new therapy. *Allergy Asthma Proc*. 2008;29(4):365-370.
15. Herth FJ. Endoscopic asthma therapy. Sense and nonsense. *Internist (Berl)*. 2008;49(11):1320-1322, 1324-1325.
16. 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.
17. Martin N, Pavord ID. Bronchial thermoplasty for the treatment of asthma. *Curr Allergy Asthma Rep*. 2009;9(1):88-95.
18. Jesudason EC. Airway smooth muscle: An architect of the lung? *Thorax*. 2009;64(6):541-545.
19. Torrego Fernández A. Bronchial thermoplasty in the treatment of asthma. *Arch Bronconeumol*. 2010;46(2):85-91.
20. Bel EH. Bronchial thermoplasty: Has the promise been met? *Am J Respir Crit Care Med*. 2010;181(2):101-102.
21. Cox G. Bronchial thermoplasty. *Clin Chest Med*. 2010;31(1):135-140.
22. Bush A, Saglani S. Management of severe asthma in children. *Lancet*. 2010;376(9743):814-825.
23. U.S. Food and Drug Administration (FDA). FDA approves new device for adults with severe and persistent asthma. *FDA News*. Silver Spring, MD: FDA; April 27, 2010. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm209909.htm>. Accessed April 30, 2010.
24. Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); June 2010.



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<http://www.guideline.gov/content.aspx?id=32556&search=asthma>. Accessed September 15, 2011.

25. Castro M, Rubin A, Laviolette M, et al; AIR2 Trial Study Group. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. *Ann Allergy Asthma Immunol*. 2011;107(1):65-70.
26. Thomson NC, Rubin AS, Niven RM, et al; AIR Trial Study Group. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. 2011a;11:8.
27. Colice GL. Emerging therapeutic options for asthma. *Am J Manag Care*. 2011;17 Suppl 3:S82-S89.
28. Oliveinstein R, Al Jahdali H, Alkhamis N, et al. Challenges in the management of severe asthma: Role of current and future therapies. *Curr Pharm Des*. 2011;17(7):703-711.
29. 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.
30. Martinez FJ, Donohue JF, Rennard SI. Chronic obstructive pulmonary disease 2: The future of chronic obstructive pulmonary disease treatment -- difficulties of and barriers to drug development. *Lancet*. 2011;378(9795):1028-1037.
31. Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of chronic obstructive pulmonary disease (COPD). Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); March 2011.
32. National Institute for Health and Clinical Excellence (NICE). Bronchial Thermoplasty for severe asthma - consultation document. London, UK: NICE; July 2011. Available at: <http://guidance.nice.org.uk/IP/675/DraftGuidance>. Accessed: September 26, 2011.
33. Thomson NC, Chaudhuri R, Spears M. Emerging therapies for severe asthma. *BMC Med*. 2011b Sep 6;9(1):102. [Epub ahead of print]
34. Torrego A, Solà I, Munoz AM, Roqué i Figuls M, Yepes-Nuñez JJ, Alonso-Coello P, Plaza V. Bronchial thermoplasty for moderate or severe persistent asthma in adults. *Cochrane Database of Systematic Reviews* 2014, Issue 3. Art. No.: CD009910. DOI: 10.1002/14651858.CD009910.pub2.
35. Burn J, Sims AJ, Keltie K, Patrick H, Welham SA, Heaney LG, Niven R. Procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics. *J Asthma*. 2016 Dec 1:0. [Epub ahead of print] PMID: 27905828 DOI: 10.1080/02770903.2016.1263652.
36. 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