02-30000-12

Original Effective Date: 08/15/10

Reviewed:08/22/24

Revised: 09/15/24

Subject: Bronchial Thermoplasty

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Bronchial thermoplasty (BT) is a procedure that delivers thermal energy to the airways via a flexible bronchoscope to ablate and reduce the mass of airway smooth muscle. Bronchial thermoplasty is intended as a supplemental treatment for patients with severe persistent asthma (i.e., steps 5 and 6 in the stepwise approach to care).

Bronchial thermoplasty procedures are performed on an outpatient basis with moderate sedation, and last approximately one hour each. During the procedure, a standard flexible bronchoscope is placed through the patient's mouth or nose into the most distal targeted airway and a catheter is inserted into the working channel of the bronchoscope. After placement, the electrode array in the top of the catheter is expanded and radiofrequency energy is delivered from a proprietary controller and used to heat tissue to 65 degrees Centigrade over a 5 mm area. The positioning of the catheter and application of thermal energy is repeated several times in contiguous areas along the accessible length of the airway. At the end of the treatment session, the catheter and bronchoscope are removed. A course of treatment consists of 3 separate procedures in different regions of the lung, scheduled approximately 3 weeks apart.

In April 2010, the Alair Bronchial Thermoplasty System (Asthmatx, Inc., Sunnyvale, CA) was approved by the FDA through the premarket approval (PMA) process for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with inhaled corticosteroids and long-acting beta agonists. Use of the treatment is contraindicated in patients with implantable devices and those with sensitivities to lidocaine, atropine or benzodiazepines. It should also not be used while patients are experiencing an asthma exacerbation, active respiratory infection, bleeding disorder, or within 2 weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty.

Summary and Analysis of Evidence: Bronchial thermoplasty is an advanced therapy for severe asthma. It is a bronchoscopic procedure in which radiofrequency energy is applied to the airway wall, resulting in decreased airway smooth muscle burden. Human trials have shown that bronchial thermoplasty may reduce asthma exacerbations and improve quality of life in patients with severe uncontrolled asthma. It has been demonstrated to be a safe procedure, with most adverse events being early and mild. More studies are required to understand the precise effects of bronchial thermoplasty on the asthmatic airway and optimal para meters to appropriately select patients for this novel procedure (Mainardi et al 2019).

In a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group, the Expert Panel states that most individuals ages 18 years and older with uncontrolled, moderate-to-severe, persistent asthma should not undergo BT to treat asthma because the benefits are small, the risks are moderate, and the long-term outcomes are uncertain. Some individuals with moderate-to-severe persistent asthma who have troublesome symptoms may be willing to accept the risks of BT and, therefore, might choose this intervention after shared decision-making with their health care provider. Clinicians should offer the procedure in the setting of a clinical trial or a registry study to enable the collection of long-term data on the use of BT for asthma (Elward, 2021).

POSITION STATEMENT:

Bronchial thermoplasty for the treatment of asthma and all other indications is considered **experimental or investigational**. There is insufficient clinical evidence published in the peer-reviewed literature regarding safety and long-term efficacy of bronchial thermoplasty on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe **(investigational)**
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes **(investigational)**

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

Stepwise approach to care: Guidelines from the National Heart, Lung and Blood Institute (NHLBI) define 6 pharmacologic steps for the treatment of asthma (step 1 for intermittent asthma, and steps 2 – 6 for persistent asthma) for individual's ≥ 12 years of age.

The preferred daily medications:

Step 1 Short-acting beta-agonists as needed;

Step 2 Low-dose inhaled corticosteroids (ICS);

Step 3 ICS and long-acting beta-agonists (LABA) or medium-dose ICS;

Step 4 Medium dose ICS and LABA;

Step 5 High-dose ICS and LABA; **AND**

Step 6 High-dose ICS and LABA, and oral corticosteroids.

RELATED GUIDELINES:

None applicable.

OTHER:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

REFERENCES:

1. Akaba T, Jo T, Iwagami M, et al. Reduced Asthma Exacerbations in Adult Patients Treated With Bronchial Thermoplasty. J Allergy Clin Immunol Pract. 2023 Oct;11(10):3076-3083.e3. [Abstract]
2. American College of Allergy, Asthma & Immunology Statement on bronchial thermoplasty, 01/01/15.
3. American College of Chest Physicians. Coverage and Payment for Bronchial Thermoplasty for Severe Persistent Asthma. May 2014.
4. Arrigo R, Failla G, Scichilone N, et al. How effective and safe is bronchial thermoplasty in "real life" asthmatics compared to those enrolled in randomized clinical trials? Biomed Research International. 2016; 2016: 9132198.
5. Allergy Foundation of America. Statement of the Asthma and Allergy Foundation of America Re: Bronchial Thermoplasty, Feb 2018.
6. Bezzi M, Solidoro P, Patella V et al. Bronchial thermoplasty in severe asthma: food for thoughts. Minerva Medica 2014; 105 (3 Suppl. 2): 7-13.
7. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.127 Diagnosis and Medical Bronchial Thermoplasty, 07/24.
8. Bicknell S, Chaudhuri R, Lee N, et al. Effectiveness of bronchial thermoplasty in severe asthma in 'real life' patients compared with those recruited to clinical trials in the same centre. Therapeutic Advances in Respiratory Disease 2015; 9(6):267-271.
9. Boulet LP , Laviolette M. Is there a role for bronchial thermoplasty in the treatment of asthma? Can Respir J. 2012 May-Jun;19 (3):191-2.

10. Brown R, Wizeman W, Danek, C, Mitzner W. Effect of Bronchial Thermoplasty on Airway Closure. Clin Med Circ Respirat Pulm Med. 2007 October 12; 1:1-6.
11. Burn J, Sims AJ, Keltie K, et al. Procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics. Journal of Asthma 2016 Dec 1.
12. Burn J, Sims AJ, Patrick H, et al. Efficacy and safety of bronchial thermoplasty in clinical practice: a prospective, longitudinal, cohort study using evidence from the UK Severe Asthma Registry. BMJ Open. Jun 19 2019; 9(6): e026742.
13. Cangelosi MJ, Ortendahi JD, Meckley LM et al. Cost-effectiveness of bronchial thermoplasty in commercially-insured patients with poorly controlled severe, persistent asthma. Expert Review of Pharmacoeconomics & Outcomes Research 2015; 15(2): 357-64.
14. 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. American Journal of Respiratory and Critical Care Medicine 2010; 181(2): 116-124.
15. Castro M, Rubin A, Laviolette ML et al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Annals of Allergy, Asthma & Immunology 2011; 107(1): 65-70.
16. Chakir J, Haj-Salem I, Gras D et al. Effects of Bronchial Thermoplasty on Airway Smooth Muscle and Collagen Deposition in Asthma. Annals of American Thoracic Society 2015; 12(11): 1612-1618.
17. 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 May;9(5):457-466. [Abstract]
18. Chung KF, Wenzel SE, Brozek JL et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. European Respiratory Journal 2014; 43(2):343-373.
19. Chupp G, Kline JN, Khatri SB, et al. Bronchial Thermoplasty in Patients With Severe Asthma at 5 Years: The Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma Study. Chest. 2022 Mar;161(3):614-628. [Abstract]
20. Chupp G, Laviolette M, Cohn L et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies. European Respiratory Journal 2017 August; 50(2).
21. Cox G, Thomson NC, Rubin AS et al. Asthma control during the year after bronchial thermoplasty. New England Journal of Medicine 2007; 356(13): 1327-1337.
22. Dheda K, Koegelenberg CFN, Esmail A et al. Recommendations for the use of bronchial thermoplasty in the management of severe asthma. South African Medical Journal 2015; 150(9): 726-732.
23. d'Hooghe JNS, van den Berk IAH, Annema JT et al. Acute Radiological Abnormalities after Bronchial Thermoplasty: A Prospective Cohort Trial. Respiration 2017; 94(3): 258-262.
24. Du Rand IA, Barber PV, Goldring J, Lewis RA, Mandal S, Munavvar M, Rintoul RC, Shah PL, Singh S, Slade MG, Woolley A, British Thoracic Society Interventional Bronchoscopy Guideline Group. British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax 2011; 66 (11): 1014-1015.
25. Elward KS. Asthma Management Guidelines: Focused Updates for 2020. Am Fam Physician. 2021 Nov 1;104(5):446-447.
26. Folch E, Mehta AC. Airway Interventions in the Tracheobronchial Tree. Semin Respir Crit Care Med. 2008; 29(4):441-452.
27. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Global Initiative for Asthma (GINA); Updated .2022

28. Gildea TR, Khatri SB, Castro M. Bronchial thermoplasty: a new treatment for severe refractory asthma. Cleve Clin J Med. 2011 Jul; 78(7):477-85.

29. Krmisky W, Sobieszczyk MJ, Sarkar S. Thermal ablation for asthma: current status and technique. Journal of Thoracic Disease 2017 2017; 9 (Suppl 2): S104-S109.

30. Langton D, Ing A, Fielding D, et al. Safety and Effectiveness of Bronchial Thermoplasty When FEV1 Is Less Than 50. Chest. 2020 Mar;157(3):509-515. [Abstract]

31. Langton D, Sha J, Ing A et al. Bronchial thermoplasty: activations predict response. Respiratory Research 2017 July; 18(1): 134.

32. Li A, Lee P. Which Endoscopic Procedure to Use and in What Patient? Valves, Coils, Foam, and Heat in COPD and Asthma. Pulm Ther. 2023 Mar;9(1):49-69.

33. Madan K, Suri TM, Mittal S, et al. A multicenter study on the safety and efficacy of bronchial thermoplasty in adults with severe asthma. Lung India. 2021 Nov-Dec;38(6):524-528.

34. Mayse ML, et al. Clinical Pearls for Bronchial Thermplasty. J Bronchol 2007; 14:115-123.

35. National Guideline Clearinghouse. Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2008 Jan. 69 p. [83 references].

36. National Heart Lung and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma, Revised Sept 2012.

37. National Institute for Health and Care Excellence. Bronchial thermoplasty for severe asthma. Interventional procedures guidance [IPG635], 2019.

38. Nishi K, Yoshimura C, Morita K, et al. Effectiveness of bronchial thermoplasty in patients with asthma exhibiting overweight/obesity and low quality of life. World Allergy Organ J. 2023 Mar 20;16(3):100756.

39. O'Reilly A, Lane S. What is the role of bronchial thermoplasty in the management of severe asthma? Therapeutic Advances in Respiratory Disease 2018 Jan-Dec; 12:1753466618792410.

40. Papakonstantinou E, Koletsa T, Zhou L, et al. Bronchial thermoplasty in asthma: an exploratory histopathological evaluation in distinct asthma endotypes/phenotypes. Respir Res. 2021 Jun 28;22(1):186.

41. Pavord ID, Cox G, Thomson C et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. American Journal of Respiratory and Critical Care Medicine 2007; 176(12): 1185-1191.

42. Pavord ID, Thomson NC, Niven RM, et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. Ann Allergy Asthma Immunol. 2013 ; 111(5):402-407.

43. Thomson NC, Rubin AS, Niven RM, Corris PA, Siersted HC, Olivenstein R, Pavord ID, McCormack D, Laviolette M, Shargill NS, Cox G, the AIR Trial Study Group. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. BMC Pulm Med 2011;11(1):8.

44. Thomson NC, Chaudhuri R, Spears M. Emerging therapies for severe asthma. BMC Med. 2011 Sep 6; 9:102.

45. Torrego A, Sola I, Munoz AM et al. Bronchial thermoplasty for moderate or severe persistent asthma in adults. Cochrane Database Systematic Review 2014 Mar 3; (3): CD009910. doi: 10.1002/14651858.CD009910.pub2.

46. U.S. Food and Drug Administration. Asthmatx, Inc. Alair Bronchial Thermoplasty System – P080032, 04/27/10.

47. Wahidi NM, Kraft M. Bronchial thermoplasty for severe asthma. American Journal of Respiratory and Critical Care 2012; 185(7): 709-14.

48. Wechsler ME, Laviolette M, Rubin A et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. Journal of Allergy and Immunology 2013; 132(6): 1295-1302.
49. Wu S, Li S, Zhang P, et al. Recent advances in bronchial thermoplasty for severe asthma: a narrative review. Ann Transl Med. 2022 Mar;10(6):370.
50. Zafari Z, Sadatsafavi M, Marra CA et al. Cost-effectiveness of bronchial thermoplasty, Omalizumab, and standard therapy for moderate-to-severe allergic asthma. PLoS One 2016; 11(1): e0146003.
51. Zein JG, Menegay MC, Singer ME et al. Cost effectiveness of bronchial thermoplasty in patients with severe uncontrolled asthma. Journal of Asthma 2016; 53(2): 194-200.
52. Zervas E, Samitas K, Papaioannou AI et al. An algorithmic approach for the treatment of severe uncontrolled asthma. EJR Open Research 2018 March; 4(1).

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

08/15/10	New Medical Coverage Guideline.
08/15/11	Annual review; position statement unchanged; references updated.
01/01/12	Annual HCPCS coding update: added 0276T and 0277T.
09/15/12	Annual review; position statement unchanged; references updated.
01/01/13	Annual HCPCS coding update: added 31660 and 31661; removed 0276T and 0277T.
09/15/13	Scheduled review; position statement unchanged; Program Exceptions section updated; references updated.
09/15/14	Annual review; position statement unchanged; Program Exceptions section updated; references updated.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/16	Review; no change in position statement. Updated description and references.
03/06/17	Updated program exceptions.
08/15/17	Review; no change in position statement. Updated references.
11/15/17	Revised position statement; added and all indications.
09/15/18	Review; revised position statement. Updated references.
08/15/19	Review; no change in position statement. Updated references.
09/15/21	Review; no change in position statement. Updated references.
09/15/23	Review; no change in position statement. Updated references.
09/15/24	Review; no change in position statement. Updated references.