MASSACHUSETTS

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Medical Policy

Bronchial Thermoplasty

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Policy Number: 284

BCBSA Reference Number: 7.01.127
NCD/LCD: N/A

Related Policies

None

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Bronchial thermoplasty, performed by a pulmonologist who has completed a bronchial thermoplasty training curriculum, may be considered **MEDICALLY NECESSARY** for patients ≥18 years when the following criteria are met:

- Patient has been diagnosed with severe persistent asthma by having any of the following criteria in the absence of controller medications:
  - Daily symptoms
  - Night time awakenings, every night
  - Use of rescue medicine multiple times per day
  - Normal activities are extremely limited
  - Impaired lung function (less than or equal to 60% predicted)
  - Frequent exacerbations, **AND**
- Co-morbid conditions contributing to asthma exacerbations have either been ruled out or fully controlled (e.g. allergy symptoms, GERD), **AND**
- Patient is taking chronic oral corticosteroids, **OR**
- Poor asthma control despite being on high-dose ICS and LABA for a minimum of 3 months with two or more asthma exacerbations per year. Asthma exacerbations are defined as follows:
  - Patient required oral systemic corticosteroid use due to respiratory symptoms, **OR**
  - Urgent provider's office visit due to severe respiratory symptoms, **OR**
  - Emergency department visit due to respiratory symptoms, **OR**
  - Hospitalization due to respiratory symptoms.

Bronchial thermoplasty is **contraindicated** for patients with the following conditions:

- Presence of a pacemaker, internal defibrillator, or other implantable electronic device
- Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine and benzodiazepines
- Patients previously treated with bronchial thermoplasty
- Active respiratory infection
- Asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) in the past 14 days
- Known coagulopathy.

Bronchial thermoplasty is considered **INVESTIGATIONAL** when the above criteria are not met.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered medically necessary when the policy guidelines above are met for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code 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

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0B538ZZ	Destruction of Right Main Bronchus, Via Natural or Artificial Opening

0B548ZZ	Destruction of Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B558ZZ	Destruction of Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B568ZZ	Destruction of Right Lower Lobe Bronchus, Via Natural or Artificial Opening
0B578ZZ	Destruction of Left Main Bronchus, Via Natural or Artificial Opening Endoscopic
0B588ZZ	Destruction of Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0B598ZZ	Destruction of Lingula Bronchus, Via Natural or Artificial Opening Endoscopic
0B5B8ZZ	Destruction of Left Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic

Description

ASTHMA

Asthma, a chronic lung disease, affects approximately 8.3% of adults and 8.3% of children in the United States and, in 2017, accounted for approximately 1.7 million emergency department visits and 3615 deaths.[1] Asthma symptoms include episodic shortness of breath that is generally associated with other symptoms such as wheezing, coughing, and chest tightness. Objective clinical features include bronchial hyperresponsiveness, airway inflammation, and reversible airflow obstruction (at least 12% improvement in forced expiratory volume in 1 second postbronchodilator, with a minimum of 200 mL improvement). However, there is substantial heterogeneity in the inflammatory features of patients diagnosed with asthma, and this biologic diversity is responsible, at least in part, for the variable response to treatment in the asthma population.

Management

Management of asthma consists of environmental control, patient education, management of comorbidities, and regular follow-up for affected patients, as well as a stepped approach to medication treatment. Guidelines from the National Heart, Lung and Blood Institute have defined 6 pharmacologic steps: step 1 for intermittent asthma and steps 2 through 6 for persistent asthma.[2] The preferred daily medications: step 1: short-acting □-agonists as-needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting □-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.

Despite this multidimensional approach, many patients continue to experience considerable morbidity. In addition to ongoing efforts to implement optimally standard approaches to asthma treatment, new therapies are being developed. One recently developed therapy is bronchial thermoplasty, the controlled delivery of radiofrequency energy to heat tissues in the distal airways. Bronchial thermoplasty is based on the premise that patients with asthma have an increased amount of smooth muscle in the airway and that contraction of this smooth muscle is a major cause of airway constriction. The thermal energy delivered via bronchial thermoplasty aims to reduce the amount of smooth muscle and thereby decrease muscle-mediated bronchoconstriction with the ultimate goal of reducing asthma-related morbidity. Bronchial thermoplasty is intended as a supplemental treatment for patients with severe persistent asthma (ie, steps 5 and 6 in the stepwise approach to care).

Bronchial thermoplasty procedures are performed on an outpatient basis, and each session lasts approximately 1 hour. 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°C 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 about 3 weeks apart.

Summary

Added to medical management, the evidence includes 3 RCTs and observational studies. Relevant outcomes are symptoms, quality of life, hospitalizations, and treatment-related morbidity. Early studies (RISA, AIR) investigated safety outcomes, finding similar rates of adverse events and exacerbations between the bronchial thermoplasty and control groups. These trials were limited by their lack of sham control. The AIR2 trial is the largest of the 3 published RCTs, and the only one double-blinded and sham-controlled, with sites in the United States. Over 1 year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome of mean change in the quality of life score but was found to be superior on a related outcome, improvement in the quality of life of at least 0.5 points on the Asthma Quality of Life Questionnaire. There was a high response rate in the sham group of the AIR2 trial, suggesting a large placebo effect, particularly for subjective outcomes such as quality of life. There are no long-term sham-controlled efficacy data.

Findings on adverse events from the 3 trials have suggested that bronchial thermoplasty is associated with a relatively high rate of adverse events, including hospitalizations during the treatment period, but not in the posttreatment period. Safety data up to 5 years have been reported in the RCTs for patients treated with bronchial thermoplasty but not for control patients. Safety data from a U.K. registry study, published in 2016, found that 20% of bronchial thermoplasty procedures were associated with a safety event (ie, procedural complications, emergency respiratory readmissions, emergency department visits, and/or postprocedure overnight stays). Conclusions cannot be drawn about the effect of bronchial thermoplasty on the net health outcome due to the limited amount of sham-controlled data (1 RCT) on short-term efficacy, the uncertain degree of treatment benefit in that single sham-controlled trial, the lack of long-term sham-controlled data in the face of a high initial placebo response, and the presence of substantial adverse events. Also, there is a lack of data on patient selection factors for this procedure and, as a result, it is not possible to determine whether there are patient subgroups that might benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
7/2018	New references added from BCBSA National medical policy. Background and summary clarified.
7/2017	New references added from BCBSA National medical policy.
10/2016	New medically necessary indications described based on expert opinion. Clarified coding information. Effective 10/1/2016.
12/2015	Added coding language.
8/2015	New references added from BCBSA National medical policy.
9/2014	New references added from BCBSA National medical policy.
7/2014	Clarified coding information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements.
11/1/2010	Medical Policy #284 effective 11/1/2010 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Centers for Disease Control & Prevention, National Center for Health Statistics. Asthma. 2017; https://www.cdc.gov/nchs/fastats/asthma.htm. Accessed May 31, 2018.
2. National Heart Lung and Blood Institute. Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2007; https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed May 31, 2018.
3. Blue Cross Blue Shield AsssociationTechnology Evaluation Center (TEC). Bronchial thermoplasty for treatment of inadequately controlled severe asthma. *TEC Assessments.* 2014;Volume 29:Tab 12. PMID 25962190
4. Pavord ID, Cox G, Thomson NC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med.* Dec 15 2007;176(12):1185-1191. PMID 17901415
5. Pavord ID, Thomson NC, Niven RM, et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. *Ann Allergy Asthma Immunol.* Nov 2013;111(5):402-407. PMID 24125149
6. Cox G, Thomson NC, Rubin AS, et al. Asthma control during the year after bronchial thermoplasty. *N Engl J Med.* Mar 29 2007;356(13):1327-1337. PMID 17392302
7. Thomson NC, Rubin AS, Niven RM, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med.* Feb 2011;11:8. PMID 21314924
8. 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.* Jan 15 2010;181(2):116-124. PMID 19815809
9. Castro M, Rubin A, Laviolette M, et al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. *Ann Allergy Asthma Immunol.* Jul 2011;107(1):65-70. PMID 21704887
10. Wechsler ME, Laviolette M, Rubin AS, et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. *J Allergy Clin Immunol.* Dec 2013;132(6):1295-1302. PMID 23998657
11. 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. *Eur Respir J.* Aug 2017;50(2). PMID 28860266
12. 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. *J Asthma.* Oct 2017;54(8):872-879. PMID 27905828
13. Langton D, Sha J, Ing A, et al. Bronchial thermoplasty: activations predict response. *Respir Res.* Jul 4 2017;18(1):134. PMID 28676053
14. d'Hooghe JNS, van den Berk IAH, Annema JT, et al. Acute radiological abnormalities after bronchial thermoplasty: a prospective cohort trial. *Respiration.* Jul 2017;94(3):258-262. PMID 28675890
15. Global Initiative for Asthma. *Global Initiative for Asthma Management and Prevention.* GINA; 2018.
16. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J.* Feb 2014;43(2):343-373. PMID 24337046
17. American College of Chest Physicians (ACCP). Position Statement for Coverage and Payment for Bronchial Thermoplasty. 2014; http://www.chestnet.org/News/CHEST-News/2014/05/Position-Statement-for-Coverage-and-Payment-for-Bronchial-Thermoplasty. Accessed May 31, 2018.
18. National Institute for Health and Care Excellence (NICE). Bronchial thermoplasty for severe asthma [IPG419]. 2012; https://www.nice.org.uk/guidance/IPG419. Accessed May 31, 2018.

Endnotes

[1] Based on expert opinion, MPG April 2016