



Louisiana

Bronchial Thermoplasty for Asthma (Alair[®])

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/12/2020

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Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers bronchial thermoplasty for the treatment of asthma to be **investigational**.*

Background/Overview

Asthma

Asthma, a chronic lung disease, affects approximately 7.7% of adults and 7.5% of children in the U. S. and, in 2018, accounted for approximately 1.6 million emergency department visits and 3564 deaths. 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 post-bronchodilator, 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. The preferred daily medications: step 1: short-acting β -agonists as-needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting β -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.

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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. A typical full course of treatment consists of 3, one hour sessions, given 3 weeks apart under moderate sedation. All accessible airways distal to the main stem bronchus that are 3 to 10 mm in diameter are treated once, except those in the right middle lobe; the lower lobes are treated first followed by the upper lung. 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).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In April 2010, the Alair[®] Bronchial Thermoplasty System (Asthmatx, now Boston Scientific) was approved by the U.S. FDA through the premarket approval process (P080032) for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with low-dose ICS and LABA. 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. FDA product code: OOOY.

Rationale/Source

Description

Thermoplasty is a potential treatment option for patients with severe persistent asthma. It consists of radiofrequency energy delivered to the distal airways with the aim of decreasing smooth muscle mass believed to be associated with airway inflammation.

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Summary of Evidence

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes 3 RCTs and observational studies. Relevant outcomes are symptoms, QOL, 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 1 double-blinded and sham-controlled, with sites in the U. S. 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 QOL score but was found to be superior on a related outcome, improvement in the QOL of at least 0.5 points on the AQLQ. 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 QOL. 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. Data from a U.K. registry showed that 20% of bronchial thermoplasty procedures were associated with a safety event (ie, procedural complications, emergency respiratory readmissions, emergency department visits, and/or post procedure overnight stays), with uncertain benefit. 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.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2014. Input was mixed on whether bronchial thermoplasty is considered investigational for the treatment of asthma; 3 reviewers agreed with this statement and 2 reviewers disagreed. Reviewers who disagreed tended to use bronchial thermoplasty in patients who had not responded to other treatments and who did not think there were treatment alternatives.

Practice Guidelines and Position Statements

Global Initiative for Asthma

Global Initiative for Asthma is an international network of organizations and professionals with expertise in asthma. The group has been updating a report entitled *Global Strategy for Asthma Management and Prevention* annually since 2002; the most recent update was issued in 2019. The organization has recommended stepped care for treatment of asthma. Options for add-on treatment in step 5 include bronchial thermoplasty for some adults with severe asthma, anti-immunoglobulin E, sputum-guided treatment, add-on low-dose oral corticosteroids, and tiotropium. The document noted that evidence on bronchial thermoplasty is limited and long-term treatment effects are unknown (level of evidence B).

American College of Chest Physicians

In May 2014, the American College of Chest Physicians posted a position statement on coverage and payment for bronchial thermoplasty. The document stated in part:

"...bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental. Randomized controlled clinical trials of bronchial thermoplasty for severe asthma have shown a reduction in the rate of severe exacerbations, emergency department visits, and days lost from school or work. Additionally, data published in December 2013 demonstrates the persistence of the reduction in asthma symptoms achieved by bronchial thermoplasty for at least 5 years...."

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2018) published guidance on bronchial thermoplasty for severe asthma. The guidance stated: "Current evidence on the safety and efficacy

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on bronchial thermoplasty 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." It was also noted that "further research should report details of patient selection and long-term safety and efficacy outcomes."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03765307 ^a	Safety and Efficacy of the SyMap Bronchial Ablation System for Treatment of Severe Asthma: A Prospective, Multicenter, Randomized Controlled Clinical Trial (Bronchial Ablation for Treatment of Asthma (BATA) Trial)	160	Feb 2021
NCT01185275	A Prospective Observational Study of Biopredictors of Bronchial Thermoplasty Response in Patients With Severe Refractory Asthma (BTR Study)	133	Dec 2021
NCT02464995	Bronchial Thermoplasty in Severe Asthma With Frequent Exacerbations (THERMASCORT)	34	Nov 2022

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03435237	Phenotyping Asthma for Bronchial Thermoplasty: Airway Smooth Muscle Structure and Function	50	Dec 2022
NCT02975284	TASMA Extension Study: Long Term Efficacy and Safety of Bronchial Thermoplasty in Severe Asthma	40	Sep 2024
NCT04077528	Research on Severe Asthma	2000	Jun 2025
<i>Unpublished</i>			
NCT02104856 ^a	Bronchial Thermoplasty Global Registry (BT Registry)	158	Jun 2019

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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07/01/2010	Medical Policy Committee review
07/21/2010	Medical Policy Implementation Committee approval. New policy.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review

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09/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/03/2020 Medical Policy Committee review

09/09/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2021

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Code Type	Code
CPT	31660, 31661

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HCPCS	No codes
ICD-10 Diagnosis	J44.0-J44.9, J45.20-J45.22, J45.30-J45.32, J45.40-J45.42, J45.50-J45.52, J45.901-J45.998

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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