Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Asthma is a long-term lung condition causing the airways of the lung to become inflamed. Inhaling certain substances such as tobacco smoke, pet dander, and dust mites can set off a chain reaction. One thing that happens during this chain reaction is that muscles around the airways constrict (tighten). This makes the airways narrower, which means less air gets into the lungs. This results in wheezing, tightness in the chest, coughing, and shortness of breath. Bronchial thermoplasty is one proposed treatment for asthma. The idea is that if there was less smooth muscle tissue around the airways, there would also be less airway constriction and fewer asthma attacks. Heat, delivered through an instrument known as a bronchoscope, is used to destroy the smooth muscle tissue. Bronchial thermoplasty is investigational (unproven). There are no long-term studies to show how well this treatment works. Longer studies are needed to see if it’s safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Service | Investigational
---|---
Bronchial thermoplasty | Bronchial thermoplasty for the treatment of asthma is considered investigational.

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
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</tr>
<tr>
<td>31660</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe</td>
</tr>
<tr>
<td>31661</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes</td>
</tr>
</tbody>
</table>

*Note:* CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

N/A

**Evidence Review**

**Description**

Bronchial 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.
Background

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. 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 all 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.

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 the 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 their airways 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 one 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 5mm 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 three separate procedures in different regions of the lung scheduled about three weeks apart.

Summary of Evidence

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes three RCTs and observational studies. The 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 three 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 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 quality of life. There are no long-term sham-controlled efficacy data. Findings on adverse events from the three 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 five 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 (one 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in **Table 1**.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<td>Ongoing</td>
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<tr>
<td>NCT02241265</td>
<td>Spirometric Response to Bronchial Thermoplasty in Patients With Severe Asthma</td>
<td>20</td>
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<tr>
<td>NCT01832363a</td>
<td>Single-Session Bronchial Thermoplasty for Severe Asthmatics Guided by HXe MRI</td>
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<tr>
<td>NCT02225392a</td>
<td>Unravelling Targets of Therapy in Bronchial Thermoplasty in Severe Asthma (TASMA)</td>
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<td>Mar 2019</td>
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<tr>
<td>NCT02104856a</td>
<td>Bronchial Thermoplasty Global Registry (BT Registry)</td>
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<td>Jun 2019</td>
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<tr>
<td>NCT01185275</td>
<td>A Prospective Observational Study of Biopredictors of Bronchial Thermoplasty Response in Patients With Severe Refractory Asthma (BTR Study)</td>
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<td>Aug 2020</td>
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<tr>
<td>NCT02464995</td>
<td>Bronchial Thermoplasty in Severe Asthma With Frequent Exacerbations (THERMASCORT)</td>
<td>34</td>
<td>Nov 2020</td>
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<tr>
<td>NCT02464995</td>
<td>Bronchial Thermoplasty in Severe Asthma With Frequent Exacerbations</td>
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<td>Nov 2020</td>
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<td>NCT03435237</td>
<td>Phenotyping Asthma for Bronchial Thermoplasty: Airway Smooth Muscle Structure and Function</td>
<td>50</td>
<td>Dec 2022</td>
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<tr>
<td>NCT02975284</td>
<td>TASMA Extension Study: Long Term Efficacy and Safety of Bronchial Thermoplasty in Severe</td>
<td>40</td>
<td>Sep 2024</td>
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</tbody>
</table>

NCT: national clinical trial.

*a Denotes industry-sponsored or cosponsored trial.
Clinical Input Received 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.

In response to requests, input was received from one physician specialty society and four 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; three reviewers agreed with this statement and two 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 (GINA) is an international network of organizations and professionals with expertise in asthma. The group has been annually updating a report entitled Global Strategy for Asthma Management and Prevention since 2002; the most recent update was issued in 2019.\textsuperscript{15} 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 effects of the treatment 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.\textsuperscript{16} 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 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.

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, now Boston Scientific) was approved by the U.S. Food and Drug Administration 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 two weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty. Food and Drug Administration product code: O0Y.

**References**


3. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Bronchial thermoplasty for treatment of inadequately controlled severe asthma. TEC Assessments. 2014; Volume 29: Tab 12. PMID 25962190


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>10/12/10</td>
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<td>09/15/11</td>
<td>Replace Policy – Policy updated with literature search. Reference numbers 6 and 9-12 added; other references renumbered or removed. No change in policy statement. ICD-10 coding added.</td>
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<td>Codes 0276T and 0277T added.</td>
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<td>CPT Codes 0276T and 0277T deleted 12/31/12; these are replaced with 31660 and 31661, effective 1/1/13, which are added to this policy.</td>
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<td>Coding Update. Code 32.27 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.</td>
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<td>06/09/15</td>
<td>Coding update: ICD-9 procedure code 32.27 added along with associated ICD-10-PCS codes in alignment with remediation efforts.</td>
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<td>Annual Review. Policy updated with literature review through June 1, 2015; reference 15 added. Policy statement unchanged.</td>
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<td>09/01/18</td>
<td>Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; references 11 and 13-14 added. Policy statement unchanged. ICD-10 PCS codes were removed from policy.</td>
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</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
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  • Qualified interpreters
  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


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Oromoo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan Idayonn. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasiyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan seten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avel depans yo. Se dwa w pou resewa enfòmasyon sa a ak asisants nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impormasion maitanggep a aplikasiyon o yonno coverage babeaen ti Premera Blue Cross. Daytoy ket malabin dagiti importante a pelta iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramideny nga addang sakbay dagiti partial a naituding nga adda aldaw tapno mapagtalainenyo ti coverage ti salun-atyo wenno tulong kadagit gastos. Adda karbenganyo a mangala ti daytoy nga impormasion ken tulong iti bukodyo a pagasasso nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):