MEDICAL POLICY – 7.01.127
Bronchial Thermoplasty

BCBSA Ref. Policy: 7.01.127
Effective Date: Aug. 1, 2017
Last Revised: July 25, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
None

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 affecting the airways of the lung. Asthma causes the airways 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

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchial thermoplasty</td>
<td>Bronchial thermoplasty for the treatment of asthma is considered investigational.</td>
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</table>

## Coding

### CPT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<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>

### ICD-10 PCS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0B538ZZ</td>
<td>Destruction of Right Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B548ZZ</td>
<td>Destruction of Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B558ZZ</td>
<td>Destruction of Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B568ZZ</td>
<td>Destruction of Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B578ZZ</td>
<td>Destruction of Left Main Bronchus, Via Natural or Artificial Opening Endoscopic</td>
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<tr>
<td>0B588ZZ</td>
<td>Destruction of Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B598ZZ</td>
<td>Destruction of Lingula Bronchus, Via Natural or Artificial Opening Endoscopic</td>
</tr>
<tr>
<td>0B5B8ZZ</td>
<td>Destruction of Left Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic</td>
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</table>

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## Related Information

N/A
Description

Bronchial thermoplasty is a potential treatment option for patients with severe persistent asthma. It consists of delivering radiofrequency energy to the airways in the lung in order to shrink the smooth muscles surrounding the airways, and thus reduce the amount of airway constriction during an asthma attack.

Background

Asthma

Asthma is a chronic lung disease affecting approximately 7.6% of adults and 8.4% of children in the United States. In 2014, asthma accounted for approximately 440,000 hospitalizations and 3650 deaths. Asthma symptoms include episodic shortness of breath that is generally associated with other symptoms such as wheezing, coughing, and chest tightness. However, patients who have asthma may have a lot of different types of symptoms, which may in part explain why asthma patients might respond differently to the same treatments.

Management

Management of asthma consists of environmental control, patient education, management of comorbidities, and regular follow-up for all affected patients. The National Heart, Lung and Blood Institute also have guidelines recommending a stepped approach to medication treatment.

Despite this multidimensional approach, there is still considerable morbidity among asthma patients. In addition to using standard best practices for asthma treatment, new therapies are being developed. One recently developed treatment 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. It is hoped that this would then reduce asthma-related morbidity. Bronchial thermoplasty is intended as a supplemental treatment for patients with severe persistent asthma.

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. A catheter is inserted into the working channel of the bronchoscope and radiofrequency energy is delivered to heat a small area of the airway tissue to 65°C. 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, with each procedure being scheduled about 3 weeks apart.

Summary of Evidence

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty, the evidence includes 3 randomized controlled trials (RCTs) and meta-analyses of these RCTs. Relevant outcomes are symptoms, quality of life, hospitalizations, and treatment-related morbidity. The AIR2 trial is the largest of the three published RCTs, and the only one that was 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 quality of life score. However, it was found to be superior on a related outcome, improvement in 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 which suggests 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 suggest 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 the 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 the 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. In addition, 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>
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<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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<td></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 2018</td>
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<tr>
<td>NCT02225392a</td>
<td>Unravelling Targets of Therapy in Bronchial Thermoplasty in Severe Asthma (TASMA)</td>
<td>40</td>
<td>Apr 2018</td>
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<tr>
<td>NCT02104856a</td>
<td>Bronchial Thermoplasty Global Registry (BT Registry)</td>
<td>160</td>
<td>Jun 2019</td>
</tr>
</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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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 through 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; 3 reviewers agreed with this statement and 2 reviewers disagreed. The reviewers who disagreed
with the policy statement 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 2017. The organization recommends stepped care for treatment of asthma. Step 1 consists of reliever inhaler use on an as-needed basis. Step 2 involves low-dose controller medication plus as-needed reliever medication. Step 3 includes 1 or 2 controllers plus as-needed reliever medication. In step 4, 2 or more controllers are used in addition to as-needed reliever medication. Step 5 involves higher level care and/or add-on treatment. According to the GINA document, 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 notes that evidence on bronchial thermoplasty is limited and long-term effects of the treatment are not known.

European Respiratory Society and American Thoracic Society

In 2014, a joint task force of the European Respiratory Society and American Thoracic Society published guidelines on the definition, evaluation, and treatment of severe asthma. The guidelines were based on a systematic review of the literature. It includes the statement: “We recommend that bronchial thermoplasty is performed in adults with severe asthma only in the context of an Institutional Review Board approved independent systematic registry of a clinical study.” The authors remarked: “This is a strong recommendation, because of the very low confidence in the available estimates of effects of bronchial thermoplasty in patients with severe asthma.”
American College of Chest Physicians

As of March 2014, the American College of Chest Physicians (ACCP) had not addressed bronchial thermoplasty in any of its national guidelines. In May 2014, ACCP posted a position statement on coverage and payment for bronchial thermoplasty. The document states 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....

British Thoracic Society and Scottish Intercollegiate Guidelines Network

In 2014, the British Thoracic Society and the Scottish Intercollegiate Guidelines Network published a revised national guideline on management of asthma. The guidelines stated, “Bronchial thermoplasty may be considered for the treatment of adult patients who have poorly controlled asthma despite optimal therapy.” The guidelines included a summary of recommended stepwise management of asthma in adults. Bronchial thermoplasty is not specifically mentioned in the stepwise management summary, but step 5 includes recommendations to consider other treatments to minimize the use of steroid tablets and to refer patients for specialty care.

National Institute for Health and Care Excellence

In 2012, the National Institute for Health and Care Excellence published guidance on bronchial thermoplasty for severe asthma. The guidance stated:

Evidence on the efficacy of bronchial thermoplasty for severe asthma shows some improvement in symptoms and quality of life, and reduced exacerbations and admission to hospital. Evidence on safety is adequate in the short and medium term. More evidence is required on the safety of the procedure in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
Medicare National Coverage

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

Regulatory Status

In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, Sunnyvale, CA, now part of Boston Scientific) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with low-dose inhaled corticosteroids and long-acting β-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.

FDA 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


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>10/12/10</td>
<td>Add to Surgery Section - New Policy</td>
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<tr>
<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-</td>
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<tr>
<td>12/29/11</td>
<td>Codes 0276T and 0277T added.</td>
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<td>09/11/12</td>
<td>Replace policy. Rationale section revised based on literature review through May 2012. References 9, 10 and 15 added; other references renumbered or removed. Policy statement is unchanged.</td>
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<td>04/15/13</td>
<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>Replace policy. Policy updated with literature search through June 11, 2013. No change in policy statement.</td>
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<tr>
<td>03/11/14</td>
<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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<tr>
<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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<tr>
<td>09/08/15</td>
<td>Annual Review. Policy updated with literature review through June 1, 2015; reference 15 added. Policy statement unchanged.</td>
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</table>

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  Email AppealsDepartmentInquiries@Premera.com

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- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room S09F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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