Bronchial Thermoplasty

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.

OBJECTIVE

The objective of this evidence review is to determine whether bronchial thermoplasty improves the net health outcome in patients with treatment-refractory asthma.

POLICY STATEMENT

Bronchial thermoplasty for the treatment of asthma is considered not medically necessary.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).
FDA 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: OOY.

RATIONALE

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, 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 three published RCTs, and the only one double-blinded and sham-controlled, with sites in the U.S. Over one 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 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.

SUPPLEMENTAL INFORMATION

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).

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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 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.

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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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy statement changed to not medically necessary.</td>
</tr>
<tr>
<td>June 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature search; References 7, 9, and 13 added. No change in policy statement</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review adding references 4, 9-10, and 14-16. Policy statement unchanged.</td>
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<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 1, 2015; reference 15 added. Policy statement unchanged.</td>
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<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 23, 2018; references 11, 13-17 and 22 added. Policy statement unchanged.</td>
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<tr>
<td>September 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 1, 2019, references added. Policy statement unchanged.</td>
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