Clinical Policy Title: Bronchial thermoplasty for severe asthma

Clinical Policy Number: CCP.1058

Effective Date: March 1, 2013
Initial Review Date: October 16, 2013
Most Recent Review Date: October 2, 2018
Next Review Date: October 2019

Related policies:
CCP.1083 Exhaled nitric oxide for the diagnosis of lung disease
CCP.1009 Pulmonary rehabilitation

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of bronchial thermoplasty for the treatment of severe or non-severe asthma to be investigational/experimental and therefore, not medically necessary.

Limitations:

All other uses of bronchial thermoplasty for the treatment of severe or non-severe asthma are not medically necessary.

Alternative covered services:

According to the National Asthma Education and Prevention Program Expert Panel Report, “Guidelines for the Diagnosis and Management of Asthma”:

- The first line of treatment for patients with severe persistent asthma is inhaled corticosteroids and long-acting beta agonists.
• If the patient does not achieve control on medium doses of corticosteroids, higher doses of inhaled corticosteroids and long-acting beta agonists are used, as prescribed by treating provider.
• There is no clear established alternative to bronchial thermoplasty (National Heart, Lung, and Blood Institute, 2007).

**Background**

Asthma is a common chronic airway disorder characterized by periods of reversible airflow obstruction, known as asthma attacks. Airflow is obstructed by inflammation and airway hyper-reactivity (contraction of the small muscles surrounding the airways) in reaction to certain exposures. Exposures include exercise; infection; allergens (e.g., pollen); occupational exposures (e.g., chemicals); and airborne irritants (e.g., environmental tobacco smoke). Symptoms may include wheezing, coughing, shortness of breath, and chest tightness. It is not clear how to prevent asthma from developing and there is no cure. Yet the means to control and prevent exacerbations in persons who have asthma are well established in evidence-based clinical guidelines (National Heart, Lung, and Blood Institute, 2018).

Currently, over 26 million Americans have asthma, including 8.3 percent of adults and 8.3 percent of children under age 18. Asthma rates have been rising for all ages, racial groups, and genders since the 1980s. Nearly half (11.5 million) of Americans with asthma reported having at least one asthma attack in 2015. Asthma accounts for 14.2 million doctor’s office visits, 439,000 hospital discharges, and 1.8 million emergency department visits (Asthma and Allergy Foundation of America, 2018).

Current guidelines emphasize that asthma therapy be selected on the basis of disease severity. For intermittent asthma, no daily medication is advised for the majority of patients. To relieve occasional symptoms, a rapid-acting, inhaled β2-agonist is prescribed. Patients with mild, persistent asthma require controller medication with a daily inhaled glucocorticoid, to achieve and maintain asthma control. Other treatment options include sustained-release theophylline, chromones, or a leukotriene modifier. For moderate persistent asthma, the preferred therapy is a combination of an inhaled glucocorticoid and a long-acting, inhaled β2-agonist. Sustained-release theophylline or a leukotriene modifier can be used instead of the β2-agonist. Primary therapy for severe, persistent asthma includes an inhaled glucocorticoid at higher doses, in addition to a long-acting, inhaled β2-agonist. Some patients with severe asthma do not achieve acceptable control despite maximal medical therapy (National Heart, Lung, and Blood Institute, 2018).

Bronchial thermoplasty is intended for the treatment of severe, persistent asthma not well controlled by long-acting bronchodilators or glucocorticoids, in patients 18 years and older. The treatment is designed to weaken and partially destroy the smooth muscle that constricts the airways during asthma attacks.

The procedure relies on a catheter that has an expandable array of electrodes and a fiber optic camera, which allows the physician to see inside the lung. After the catheter is threaded into the airway, a wire
leading out of the back end of the catheter is attached to a radiofrequency generator, and a lever is operated that causes the electrodes to curl into a ball shape around the front end of the catheter. The curved electrodes are held against the bronchial walls and an electrical current is applied to generate heat that destroys the smooth muscle underneath the lining of the bronchial passages (Mayse, 2007).

The complete thermoplasty procedure is performed in three treatment sessions targeting different segments of the lung, with a recovery period of ≥ 3 weeks between each session. Bronchial thermoplasty is typically performed by a pulmonologist, with the patient under moderate sedation or general anesthesia. The use of bronchial thermoplasty was evaluated in three randomized controlled trials supported by the manufacturer of the Alair™ Bronchial Thermoplasty System (Boston Scientific Corporation, 2018). The device was approved by the U.S. Food and Drug Administration in April 2010.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 8, 2018. Search terms were “asthma” and “bronchial thermoplasty.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

A number of guidelines from professional societies support the use of bronchial thermoplasty as an add-on treatment for selected patients with severe asthma (Global Initiative for Asthma, 2017; Health Improvement Scotland, 2016; American College of Allergy, Asthma, and Immunology, 2015; American College of Chest Physicians, 2014; INTERASMA, 2014). However, some of these sources caution that the evidence supporting use of this treatment is limited, and that clinicians should carefully advise patients of potential risks and benefits before therapy begins.
A review by the Agency for Healthcare Quality and Research evaluated 15 studies (n = 432), three of which were randomized controlled trials, for persons with severe asthma. Outcomes after bronchial thermoplasty plus standard care (continued medical management) versus sham bronchial thermoplasty plus standard care were compared. Asthma control, hospitalizations for respiratory symptoms, use of rescue medications, pulmonary physiology measures, or quality of life scores were not significantly different between the two groups. Bronchial thermoplasty, compared with sham thermoplasty or standard care was linked with fewer severe exacerbations and emergency visits, but also with higher rates of hospitalization (D’Anci, 2017).

A Cochrane review of three randomized controlled trials of 249 patients with severe persistent asthma compared bronchial thermoplasty with medical management or a sham intervention (Torrego, 2014). Results affirmed those in a meta-analysis three years prior (Wu, 2011), and showed that bronchial thermoplasty, in comparison with other groups:

- Improved quality of life at 12 months, a finding not clinically significant
- Had the same level of symptoms control
- Showed a lower rate of exacerbation and emergency department visits (8.4 versus 15.3 percent) after 12 months
- Documented no significant improvement in pulmonary function parameters (with the exception of a greater increase in morning peak expiratory flow in one trial)
- Had a significantly greater hospitalization risk for respiratory adverse events during treatment (risk ratio 3.50, representing an increase from 2 to 8 percent over the treatment period
- Was associated with a rise in respiratory adverse events, mainly during the treatment period.

Of the bronchial thermoplasty subjects in the meta-analysis, 216 were followed for five years after treatment. The frequency of respiratory adverse events were significantly reduced (P < .00001). The number of emergency visits and hospitalizations for adverse events were (non-significantly) changed at P = .71 and P = .32 (Zhou, 2016).

A systematic review of three trials evaluated the efficacy of bronchial thermoplasty with omalizumab (Xolair), a monoclonal antibody to treat asthma, both compared with sham treatments or placebo. Bronchial thermoplasty patients experienced fewer severe exacerbations (P = .62) and hospitalizations (P = .53) but significantly fewer emergency department visits (P = .04). Scores on the asthma quality-of-life questionnaire were insignificantly higher for the bronchial thermoplasty group (P = .059). The rate of exacerbations for bronchial thermoplasty was significantly higher at P < .009 (Niven, 2018).

The randomized controlled trials that made up the above systematic reviews and meta-analyses include a small trial from the United Kingdom, known as the Research in Severe Asthma trial. A five-year follow-up of 14 asthma patients taking bronchial thermoplasty along with corticosteroids and ß2 agonists compared outcomes for year 1 to year 2–5 after bronchial thermoplasty treatment. No changes were observed for adverse events or in lung function, and declines in hospitalizations and emergency visits for respiratory symptoms were observed (Pavord, 2013). These five-year findings matched those from the first year post-treatment (Pavord, 2007).
A second, and also small, trial of bronchial thermoplasty is known as the Asthma Information Research trial. A randomized controlled trial of 45 patients treated with bronchial thermoplasty and 24 control patients not given bronchial thermoplasty reviewed five-year outcomes. Respiratory adverse events per subject for the five years after bronchial thermoplasty treatment were 4.5, 1.2, 1.3, 1.2, and 1.1, not different than the 3.1, 1.2, and 1.3 figures for controls (which were not followed in years 4-5). There was no elevated rate in hospital or emergency room visits for respiratory symptoms in years 2-5 for the bronchial thermoplasty group (Thomson, 2011). The trial confirmed results for the 12 month post-treatment period (Cox, 2007).

The third, and largest of the three randomized controlled trials is known as AIR2. It first compared 190 subjects in the bronchial thermoplasty group and 98 in the sham group one year after treatment. Bronchial thermoplasty consistently showed superior efficacy in net benefit in Asthma Quality of Life Questionnaire score (76 versus 57 percent), percent with severe exacerbations (26.3 versus 39.8), days per year lost from work and school (1.32 versus 3.92), percent of subjects with adverse respiratory events reported (70 versus 80), and emergency visits per subject per year for respiratory symptoms (0.07 versus 0.43) (Castro, 2010). Similar results were observed after the second year post-treatment (Castro, 2011).

A more recent report updated AIR2 results, and compared results in the year prior to treatment with the five years after treatment. A 48 percent reduction in exacerbation and 88 percent reduction in emergency visits in the bronchial thermoplasty group were both significant. No changes were observed in pre- bronchial thermoplasty, Forced Expiratory Volume or respiratory-related adverse events, and hospitalizations (Weichsler, 2013).

Policy updates:

A total of five clinical guidelines/other and one peer reviewed reference were added to, and four clinical guidelines/other were removed from this policy in August 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>D’Anci (2017)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Effectiveness and safety of bronchial thermoplasty</td>
<td>• A review by the Agency for Healthcare Quality and Research of 15 studies (n = 432).</td>
</tr>
<tr>
<td></td>
<td>• All patients had severe asthma, three of were randomized controlled trials.</td>
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<tr>
<td></td>
<td>• Bronchial thermoplasty and standard care compared to standard care (continued medical management) alone improved Asthma Quality of Life Questionnaire scores significantly, but this had no clinical importance.</td>
</tr>
<tr>
<td></td>
<td>• Studies that compared outcomes after bronchial thermoplasty plus standard care (continued versus sham bronchial thermoplasty plus standard care found asthma control, hospitalizations for respiratory symptoms, use of rescue medications, pulmonary physiology measures, or quality of life scores were no different between the two groups.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</tbody>
</table>
| **Zhou (2016)**<br>Summary of bronchial thermoplasty trials five years after treatment | - Studies also found that bronchial thermoplasty was linked with fewer severe exacerbations and emergency visits.  
- Studies found higher rates of hospitalization (significant) in the bronchial thermoplasty group, along with insignificantly higher rates of upper respiratory tract infections, wheezing, dyspnea, lower respiratory tract infections, anxiety, and segmental atelectasis, |
| **Torrego (2014)**<br>Summary of bronchial thermoplasty trials one year after treatment | **Key points:**  
- Meta-analysis of 216 persons with severe asthma given bronchial thermoplasty versus standard medical management or sham treatment, followed five years after treatment.  
- Bronchial thermoplasty was associated with reduced frequency of respiratory adverse events were (rate ratio (RR) 3.41, $P < .00001$).  
- The number of emergency visits and hospitalizations for adverse events were unchanged at RR $= 1.06$ ($P = .71$) and RR $= 1.47$ ($P = .32$). |
| **Wechsler (2013)**<br>Large trial of bronchial thermoplasty five years after treatment | **Key points:**  
- Randomized controlled trial updating 2010 study, comparing bronchial thermoplasty versus sham treatment efficacy five years after treatment.  
- A 48% reduction in exacerbation and 88 percent reduction in emergency visits in the BT group were both significant.  
- No changes were observed in pre-bronchial thermoplasty Forced Expiratory Volume or respiratory-related adverse events, and hospitalizations. |
| **Castro (2010)**<br>Large trial of bronchial thermoplasty one year after treatment | **Key points:**  
- Randomized controlled trial of 190 subjects given bronchial thermoplasty and 98 given sham treatment.  
- One year after treatment, patients in the bronchial thermoplasty group consistently showed superior efficacy in net benefit in Asthma Quality of Life Questionnaire score (76 versus 57 percent), percent with severe exacerbations (26.3 versus 39.8), days per year lost from work and school (1.32 versus 3.92), percent of subjects with adverse respiratory events reported (70
versus 80), and emergency visits per subject per year for respiratory symptoms (0.07 versus 0.43).

References

Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<thead>
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<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>31660</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial Thermoplasty, one lobe.</td>
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<tr>
<td>31661</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, two or more lobes.</td>
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<tr>
<td>J44.0</td>
<td>Chronic obstructive pulmonary disease with acute lower respiratory Infection</td>
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<tr>
<td>J44.1</td>
<td>Chronic obstructive pulmonary disease with (acute) exacerbation</td>
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<td>J44.9</td>
<td>Chronic obstructive pulmonary disease, unspecified</td>
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<td>Mild intermittent asthma with (acute) exacerbation</td>
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<td>J45.41</td>
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<td>J45.42</td>
<td>Moderate persistent asthma with status asthmaticus</td>
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<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
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<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
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<td>J45.52</td>
<td>Severe persistent asthma with status asthmaticus</td>
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<td>J45.901</td>
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<td>J45.909</td>
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<td>J45.990</td>
<td>Exercise induced bronchospasm</td>
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<td>J45.998</td>
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