Clinical Policy Title: Bronchial thermoplasty for severe asthma

Clinical Policy Number: 07.03.01

Effective Date: March 1, 2013
Initial Review Date: October 16, 2013
Most Recent Review Date: October 19, 2016
Next Review Date: October 2017

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas Iowa has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Iowa’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 AmeriHealth Caritas Iowa 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. AmeriHealth Caritas Iowa’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. AmeriHealth Caritas Iowa’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Iowa will update its clinical policies as necessary. AmeriHealth Caritas Iowa’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Iowa considers the use of bronchial thermoplasty (BT) for the treatment of severe or non-severe asthma to be investigational and, therefore, not medically necessary.

Limitations:

All other uses of BT 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 (NAEPP) 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 (ICS) and long-acting beta agonists (LABA).
• If the patient does not achieve control on medium doses of corticosteroids, higher doses of ICS and LABA are used, as prescribed by treating provider.
• There is no clear established alternative to BT.

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.

In 2010, an estimated 25.7 million Americans had asthma — 18.7 million adults ages 18 and over, and 7.0 million children, ages 0 – 17 years. In the last decade, the proportion of people with asthma in the United States grew by nearly 15 percent. In 2009, asthma caused:

• Hospitalizations: 479,300.
• Emergency room visits: 1.9 million.
• Doctor’s visits: 8.9 million.

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.

BT is intended for the treatment of severe, persistent asthma not well controlled by long-acting bronchodilators or glucocorticoids, in patients ages 18 years and older. BT 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.

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. BT is typically performed by a pulmonologist, with the patient under moderate sedation or general anesthesia. The use of BT was evaluated in three randomized controlled trials (RCTs) supported by the manufacturer of the Alair™ Bronchial Thermoplasty System (Boston Scientific Corporation, Natick, MA/Asthmatx Inc., Sunnyvale, California.) (See the clinical trial section.)

**Searches**

AmeriHealth Caritas Iowa 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 (CMS).

We conducted searches on September 16, 2016. Search terms were “asthma” and “BT.”

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**

The three available RCTs that evaluated BT for the treatment of asthma provide evidence that, in the short term, bronchial therapy appears reasonably safe and somewhat effective for patients who have severe asthma. Treatment with thermoplasty was associated with statistically significant increases in complications, including dyspnea, wheezing, chest discomfort, night awakenings, sputum discoloration, cough, and productive cough during the treatment period, but most of these complications were mild or moderate in severity. During the first year after thermoplasty, benefits — including improved quality of life, symptom relief, reduced medication use, and reductions in emergency room visits — were observed; however, the benefits varied somewhat in the three RCTs.
These differences in benefits may have resulted from differences in study protocols, because the two smaller RCTs involved partial discontinuation of certain asthma medications. Although observation of benefits of thermoplasty after medication reduction may give a more accurate representation of the clinical situation and a desire to minimize medication usage and associated side effects of medications, reduction of medication for the control group may have exaggerated symptoms and lead to an overestimation of the benefits of thermoplasty.

Only one of the RCTs reported results of controlled follow-up for longer than one year. This study found that, at three years’ follow-up, the only statistically significant benefit of thermoplasty was an improvement in airway responsiveness. However, this follow-up may have been flawed, since it involved only 69 patients and the drop-out rate was much higher for the control group than for the thermoplasty group. The apparent loss of thermoplasty benefit during longer follow-up may indicate loss of effectiveness over time, or may be a result of control group patients’ selective dropping out, who have the least well-controlled asthma. Additional controlled studies are needed to assess the long-term safety and efficacy of BT for the treatment of asthma.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Pavord (2013) | **Key points:**
| | • 14 patients with severe asthma, ages 18 – 65, uncontrolled symptoms.
| | • Five-year follow-up, comparing each year versus year before BT initiated.
| | • Annual respiratory adverse events years 2 – 5 = 1.4, 2.4, 1.7, 2.4.
| | • Reduction in hospitalizations and emergency room visits. |
| Weichsler (2013) | **Key points:**
| | • 162 given BT for five years.
| | • Compared to the year before therapy, 44% reduction in exacerbations, 78% reduction in emergency room visits.
| | • Respiratory adverse events and respiratory-related hospital admissions did not change from the first year to the second – fifth years. |
| National Institute for Health and Clinical Excellence (NICE) 2012 | **Key points:**
| | • For patients with severe asthma, BT has been shown to provide some improvements in symptoms and quality of life, as well as reductions in exacerbations and hospital admissions.
| | • Although evidence of safety is adequate in the short and medium term, more evidence of long-term safety is needed; therefore, thermoplasty should only be used after establishment of special arrangements for clinical governance, including patient consent and research or audit.
| | • The NICE encourages additional research to evaluate the long-term safety and efficacy of thermoplasty (NICE) 2012. |
### Key points:

- **British Thoracic Society (BTS) 2012**
  - For patients who have moderate to severe asthma, BT has been associated with a short-term increase in symptoms related to asthma.
  - This procedure reduces symptoms, beginning approximately six weeks after the final thermoplasty treatment.
  - Specific benefits of this procedure are fewer asthma exacerbations, improvements in quality of life, and fewer days lost from work or school due to asthma.
  - The BTS recommends thermoplasty as a potential treatment option in carefully selected patients who have severe, persistent asthma and who are on maximal therapy.
  - Despite this recommendation, the BTS cautions that long-term safety and efficacy of thermoplasty are unclear, so the clinical role of thermoplasty in asthma remains to be established, and this treatment should only be performed at a limited set of specialty centers.
  - The BTS also recommends longer-term follow-up of patients who undergo thermoplasty (BTS 2012).

- **California Technology Assessment Forum (CTAF) (2012)**
  - Although the benefits of treatment were limited, net improvements were sufficient to recommend this procedure in patients who have few other options.
  - A particular concern of the CTAF is the potential long-term sequelae of thermoplasty, since few patients have undergone at least five years of follow-up after this procedure (CTAF 2012).

- **Global Initiative for Asthma (GINA) (2012)**
  - This treatment exacerbates asthma during the months following treatment, but results in a subsequent decrease in exacerbations without significantly affecting lung function or asthma symptoms.
  - The long-term safety and efficacy of thermoplasty are not known and GINA recommends caution be used in the selection of patients for this procedure (GINA 2011).

- **Thomson (2011)**
  - 45 treated and 24 control subjects.
  - Respiratory adverse events of the second – fifth years were 1.2, 1.3, 1.2, and 1.1.
  - No increase in hospital admissions or emergency visits in the second – fifth years.

### Glossary

**Alair™ Bronchial Thermoplasty System (Asthmatx Inc.)** — The Alair Bronchial Thermoplasty System treats severe persistent asthma by delivering thermal radiofrequency energy to the airway wall, which heats the tissue in a controlled manner and reduces airway smooth muscle mass (muscle thickness). Patients are treated in multiple sessions that target different areas of the lungs.
**Asthma** — A chronic disorder of the airways, characterized by episodes of impaired breathing. Asthma is caused by airflow obstruction, due to bronchial hyper-responsiveness and underlying inflammation.

**Bronchial thermoplasty (BT)** — A bronchoscopic procedure that uses radiofrequency ablation to reduce the mass of airway smooth muscle (ASM), thus attenuating bronchoconstriction.

**Extrinsic asthma** — Asthma caused by some factor in the environment, usually atopic in nature.

**Status asthmaticus** — A particularly severe asthmatic attack that does not respond adequately to usual therapy and may require hospitalization.

**References**

**Professional society guidelines/other:**


Centers for Disease Control and Prevention’s (CDC) National Center for Health Statistics, Office of Analysis and Epidemiology. Lara J. Akinbami and Xiang Liu.


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on September 15, 2016, using the term “bronchial thermoplasty” | Open Studies. Nine studies found, two relevant:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs 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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