



**BRONCHIAL THERMOPLASTY (ALAIR® SYSTEM)
FOR THE TREATMENT OF SEVERE ASTHMA
HS-170**



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**Bronchial Thermoplasty
(Alair® System) for the
Treatment of Severe Asthma**

Policy Number: HS-170

Original Effective Date: 5/20/2010

Revised Date(s): 6/16/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Asthma is a complex chronic disorder that causes narrowing of the airways. It affects more than 22 million people in the United States, of which 16 million are adults. The condition is typically characterized by episodes of bronchial hyper-responsiveness, underlying airway inflammation, and obstructed breathing. Asthma symptoms are treatable with fastidious medical management, but there is no known cure for the disease.

Inhaled corticosteroids (ICS) and long-acting beta 2-adrenergic agonists (LABA) are now the mainstay agents in the control of asthma symptoms. ICS are effective in suppression of airway inflammation, but typically do not control virus-induced exacerbations and are not beneficial in asthma patients who smoke. LABA are currently used as an adjunct therapy for asthma that is not well controlled by ICS. Combination inhalers containing ICS and LABA are increasingly popular in the United States.

In an estimated 20% to 30% of adult asthma patients, symptoms are not adequately managed with current care agents. This is partly attributed to inconsistent patient compliance with treatment regimens. However, approximately 10% of the asthma patient population has true refractory disease that cannot be well controlled despite optimal adherence to treatment. Effective treatment options for these patients are lacking. Bronchial thermoplasty is among the many new therapies being developed to address this unmet need.

Description

The Alair System is indicated for the adjuvant treatment of severely symptomatic asthma in patients whose disease cannot be adequately managed with current care drug regimens despite optimal adherence. Current care regimens include high doses of inhaled corticosteroids (ICS) and long-acting beta 2-adrenergic agonists (LABA). The procedure is not a cure for asthma, nor will it obviate the need for continued medical management of the disease.

The Alair System consists of a radiofrequency generator and a single-use catheter that is sized to fit through a standard flexible bronchoscope. At the tip of the catheter is an expandable four-electrode basket that is designed to rest snugly against targeted intraparenchymal airways while it delivers controlled radiofrequency energy. The catheter is introduced through a fiber optic bronchoscope that is threaded through the patient's nose or throat. Currently, a complete course of treatment is administered in a series of 3 procedures every 3 weeks, with each procedure lasting approximately 30 to 60 minutes. However, a small study is under way to evaluate the safety of performing bronchial thermoplasty with the Alair System during two treatment sessions.

The goal of this procedure is reduction of airway smooth muscle. It is theorized that reducing airway smooth muscle mass will diminish the ability of targeted muscles to contract, thereby improving the severity and frequency of asthma symptoms.

Bronchial thermoplasty with the Alair System is an outpatient procedure performed in a hospital bronchoscopy suite by physicians specially trained in the technique. The patient is usually given conscious sedation, although general anesthesia may be used in some cases. The procedure specifically treats tissue in airways larger than 3 mm in diameter beyond the lobar bronchi, which is accessible and visualized with a standard bronchoscope. It cannot access and treat peripheral airways. After each treatment session, patients are monitored for at least 6 hours.

Results of the available studies provide preliminary evidence that bronchial thermoplasty is reasonably safe and has some efficacy for treatment of asthma. The largest available randomized controlled trial (RCT) found that thermoplasty was superior to sham therapy in mean Asthma Quality of Life Questionnaire score even though the improvement was small. Thermoplasty was also superior to sham therapy for reducing emergency department visits during the first year after treatment (a 72% reduction). Although these results are promising, this study found that thermoplasty was not superior to sham therapy in several other measures of asthma severity including the mean Asthma Control Questionnaire score, mean number of severe asthma exacerbations, and mean total

symptom score. Two smaller RCTs found statistically significant improvements in various measures of asthma severity 1 year after treatment; however, the efficacy of thermoplasty might have been overestimated since certain medications for asthma control were reduced or discontinued. Furthermore, the available controlled studies involved only 1 year of assessment of results after initiation of treatment; therefore, the long-term safety of thermoplasty and durability of improvements obtained with this procedure are unknown. The efficacy and safety of bronchial thermoplasty for retreatment of the same areas of the lung have not been established. Additional studies are needed to confirm that bronchial thermoplasty benefits patients who have asthma and to evaluate its long-term safety and effectiveness.

A study by the manufacturer looking at safety showed no significant differences between the treatment group and the control group at 3 years. The treatment group was followed for two more years without an increase in adverse events. However it should be noted that other than response to MTC, there was also no significant differences in outcomes at 3 years, including ER visits or hospitalizations.

Regulatory Status

On April 27, 2010, the FDA approved a PMA application for the Alair System.. The device is indicated for use in patients ages 18 or older whose severe and persistent asthma is not well controlled with inhaled corticosteroids and long-acting beta agonist medications. The FDA warns that the Alair System should not be used in patients with an implantable electronic device, and those patients with known sensitivities to lidocaine, atropine, or benzodiazepines. The agency further notes that the Alair has not been studied for efficacy in retreatment of the same area of the lung. As a condition of its approval, the FDA is requiring the manufacturer to conduct a 5-year post-market study of the Alair System to evaluate long-term safety and effectiveness. The Alair System for bronchial thermoplasty is the first surgical treatment option commercially available in the United States for the management of asthma. The device has received CE Marking for sale in the European Union.

Conclusion

There is some evidence that bronchial thermoplasty with the Alair System may be a reasonable new treatment option for severe and persistent asthma; however, there is insufficient available evidence at this time to establish long-term safety or efficacy. The role of smooth muscle in the airway wall is not fully understood, and it remains to be proven whether or not reduced muscle mass in selected channels will result in reduced contractile sensitivity to asthma triggers, or in improved disease-related symptoms in the long term. Patient selection criteria for bronchial thermoplasty with the Alair System have not been defined, although the procedure is currently performed only in adult nonsmokers who have persistent and severe asthma despite optimal medical management (Hayes, 2010).

POSITION STATEMENT

The Alair® Bronchial Thermoplasty System (Asthmatx, Inc.) **is considered experimental and investigational for the treatment of severe asthma and is NOT a covered benefit.**

CODING

Non-Covered CPT® Code

94799 Unlisted pulmonary service or procedure

ICD-9-CM Procedure Codes - Not applicable

HCPCS Level II Code - No applicable code

Clinical Coverage Guideline

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Non-Covered ICD-9-CM Diagnosis Codes

493.00 - 493.02 Asthma, Extrinsic;
493.10 - 493.12 Asthma, Intrinsic,
493.20 - 493.22 Asthma, Chronic Obstructive
493.80 - 493.82 Other forms of Asthma; Exercise Induced Bronchospasm; Cough Variant Asthma
493.90 - 493.92 Asthma, Unspecified; Bronchial, Allergic, Asthmatic

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Castro M, Rubin AS, Laviolette M, Fiterman J, De Andrade Lima M, Shah PL, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. *Am J Respir Crit Care Med.* 2010;181(2):116-124.
2. Cox G, Thomson NC, Rubin AS, Niven RM, Corris PA, Siersted HC, et al.; AIR Trial Study Group. Asthma control during the year after bronchial thermoplasty. *N Engl J Med.* 2007;356(13):1327-1337.
3. Cox G, Miller JD, McWilliams A, Fitzgerald JM, Lam S. Bronchial thermoplasty for asthma. *Am J Respir Crit Care Med.* 2006;173(9):965-969.
4. Hayes Technology Brief, October 20, 2010
5. Holgate ST, Polosa R. Treatment strategies for allergy and asthma. *Nat Rev Immunol.* 2008;8(3):218-230.
6. Martin N, Pavord ID. Bronchial thermoplasty for the treatment of asthma. *Curr Allergy Asthma Rep.* 2009;9(1):88-95.
7. Miller JD, Cox G, Vincic L, Lombard CM, Loomas BE, Danek CJ. A prospective feasibility study of bronchial thermoplasty in the human airway. *Chest.* 2005;127(6):1999-2006.
8. Pavord ID, Cox G, Thomson NC, Rubin AS, Corris PA, Niven RM, et al.; RISA Trial Study Group. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med.* 2007;176(12):1185-1191.
9. Thomson et al. BMC Pulmonary Medicine 2011, 11:8 Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial

Government Agencies, Professional and Medical Organizations

1. National Heart Lung and Blood Institute (NHLBI) [website]. Expert Panel Report 3 (EPR3): Guidelines for the Diagnosis and Management of Asthma. Updated August 5, 2008. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>. Accessed April 28, 2010.

Other

1. Asthmatx Inc. RISA Extension Study - Long Term Safety. National Library of Medicine (NLM) Identifier: NCT00401986. Updated December 4, 2008. ClinicalTrials.gov [website]. Available at: <http://clinicaltrials.gov/show/NCT00401986>. Accessed April 28, 2010.
2. Asthmatx Inc. Safety of Bronchial Thermoplasty Performed With the Alair® System During Two Treatment Sessions to Treat Severe Asthma (3to2). National Library of Medicine (NLM) Identifier: NCT00803088. Updated February 10, 2010. ClinicalTrials.gov [website]. Available at: <http://clinicaltrials.gov/show/NCT00803088>. Accessed April 28, 2010.



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HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
6/16/2011	<ul style="list-style-type: none">• Approved by MPC.