



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Bronchial Thermoplasty for Treatment of Severe Bronchial Asthma

- Alair Bronchial Thermoplasty System

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc., provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in their benefits. Always consult the patient's Medical Coverage Agreement or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* (A-0634) for medical necessity determinations. This service is not covered per MCG guidelines.

***MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (pulmonary/allergy)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Asthma is an increasingly prevalent disease that affects over 20 million people in the United States. It is estimated that 15 -20% of asthma patients have a severe condition despite receiving the new effective therapies. Asthma is characterized by chronic inflammation of the airways, airway wall edema, bronchial hyper responsiveness, and remodeling of the airways that include increased airway smooth muscle mass. Each of these factors alone or in combination can result in recurrent episodes of wheezing, coughing, chest tightness, and breathlessness (Castro 2010, Cox 2011).

Although inflammation of the airways is a main feature of asthma, researchers believe that the contraction of the excess airway smooth muscles, in response to various asthma triggers, is the main cause of airway constriction and restricted airflow leading to breathing difficulty during asthma attacks. This led to a hypothesis that decreasing the mass and /or contractility of airway smooth muscle would reduce airway bronchoconstriction and ameliorate the symptoms of asthma. Based on this hypothesis, investigators suggested that the application of thermal energy to the airway wall, termed bronchial thermoplasty, can reduce the bronchoconstrictor response in asthma (Cox 2007, Pavord 2007, Wechsler 2008).

Bronchial Thermoplasty (BT) is a device-based approach for severe persistent asthma that involves the application of controlled heat from a radiofrequency (RF) source to the airway wall resulting in a prolonged reduction in airway smooth muscle mass. The Alair System (Asthmax Inc., Sunnyvale, CA) is the first device designed to use RF to

selectively reduce the amount of excess airway smooth muscle in airways distal to the main stem bronchi down to 3 mm in diameter. The Alair system consists of the Alair RF catheter that has an expandable electrode array on the tip, and the Alair RF controller which supplies energy via the catheter to heat the airway wall. The catheter is deployed under direct vision through a compatible flexible bronchoscope, which is navigated to the first target treatment site, typically the most distal airway in the targeted lobe. Once the bronchoscope is inserted in the airways, the catheter is passed through the bronchoscope and its electrode array expanded such that all its sides are in contact with the airway wall. The bronchoscopist steps on a footswitch attached to the RF controller for approximately 10 seconds. This delivers low-power, temperature-controlled RF thermal energy to the treated airway. A single activation of the catheter delivers RF energy over a distance of approximately 5 mm. The catheter is then repositioned so that other adjacent areas of the airways may be treated, following a mapped treatment plan, and avoiding overlap. All visible and reachable airways 3-10 mm in diameter that are distal to the main stem bronchi are treated with a series of contiguous activations. A systematic approach from distal to proximal, working methodologically from airway to airway across the lung being treated is recommended to ensure that all accessible airways are carefully identified and treated only once. BT is performed under conscious sedation in an outpatient setting, and the procedure takes 30-45 minutes to complete. The treatment is administered in three sessions approximately 3 weeks apart. A different region of the lung is treated during each session: one lower lobe in session 1; the second lower lobe in session 2; and both upper lobes in session 3. Depending on the patient size and anatomy, a range of approximately 60-100 energy cycles are performed (Duhamel 2010, Wechsler 2008, Castro 2010).

Patients are selected for BT by an asthma specialist and an experienced bronchoscopist, and should not be considered for the procedure if they have acute respiratory infection, known coagulopathy, active respiratory infection, or with asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) 14 days before the procedure (Duhamel 2010).

This Alair Bronchial Thermoplasty system received marketing clearance from the U.S. Food and Drug Administration (FDA) in April 2010 for the control of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The FDA approved the system based on data from AIR2 trial, and is requiring a five-year post-approval study of the device to study its long-term safety and effectiveness. The FDA list of potential adverse events associated with the use of the device includes: upper respiratory tract infection, throat irritation, pharyngolaryngeal pain, rhinitis, nasopharyngitis, asthma (multiple symptoms), sinusitis, wheezing, dyspnea, airway bleeding, cough, laryngospasm, bronchospasm, bronchitis, excess mucus production, chest discomfort, increased airway reactivity, atelectasis, hemoptysis, bronchial stenosis, bronchiectasis, pneumothorax, and others.

Medical Technology Assessment Committee (MTAC)

Bronchial Thermoplasty

04/18/2011: MTAC REVIEW

Evidence Conclusion: The Asthma Intervention Research (AIR) trial examined the efficacy of BT in patients with moderate to severe asthma while AIR2 and Research in Severe Asthma (RISA) trials studied the efficacy of the procedure in patients with symptomatic severe asthma despite the use of high doses of inhaled corticosteroids (ICS) and long acting β_2 adrenergic agonists (LABA). AIR and RISA trials compared BT in addition to usual care with standard medications versus usual care alone, and had no sham control. The AIR2 trial compared the BT to sham therapy, which was an advantage of the trial as it addressed the concern about the placebo effect of bronchial thermoplasty in the control of severe asthma. All three trials were supported by Asthmatx Inc., the manufacturer of Alair Bronchial Thermoplasty System, and the authors had financial ties to the industry and other pharmaceutical companies. The AIR trial conducted by Cox and colleagues ([Evidence Table 1](#)) enrolled 112 patients aged 18 to 65 years with moderate to severe asthma symptoms despite receiving combined therapy with ICS and LABA, and in whom the withdrawal of LABAs resulted in a worsening of asthma control. Eligible patients were randomly allocated to a treatment group that received BT in addition to the standard therapy, or to a control group that only received the standard treatment. Initially the patients were followed up for 12 months after which they were invited to participate in a 4-year safety study. The primary outcome for the first 12 months was the difference between the BT group and the controls in the change in rate of mild exacerbation between baseline and later time points. The trial results showed a significant difference between the BT group and the controls in the change of mild exacerbations rate from baseline to three months and 12 months. No such significant difference between the two treatment groups was observed for severe exacerbations. The 5-year follow-up of 80% of patients in the BT group showed no increase in rate of hospitalization or emergency department visits for respiratory symptoms in years 2 to 5 compared to year one. The AIR2 trial by Castro and colleagues ([Evidence Table 2](#)) enrolled 288 highly selected patients with severe symptomatic asthma despite treatment with high doses of ICS and LABA. They were randomized in a 2:1 ratio to receive BT or sham therapy in which the controls underwent three bronchoscopies and sham thermoplasty treatment that duplicated the BT procedure except for the delivery of radiofrequency energy. Patients were followed-up for 12

months and the primary outcome was improvement in Asthma Quality of Life Questionnaire (AQLQ) at 6, 9, and 12 months. Both the BT and sham therapy groups experienced a large improvement in the AQLQ that lasted for 12 months. The absolute difference between the two groups was statistically significant, but was too small and might not be clinically relevant. Other secondary outcomes including the Asthma Control Questionnaire (ACQ) score, symptom scores, airflow, airway hyper responsiveness, and rescue medication use showed a trend towards more improvement with BT over sham treatment, but none was statistically significant. The authors did not study the effect of BT on step-down of maintenance asthma medications, which according to the national guidelines is the main goal in the long-term management. Both AIR and AIR2 trials show that BT therapy temporarily aggravated asthma symptoms and increased the risk of adverse events some of which required hospitalization.

Articles: The literature search revealed around 30 articles on bronchial thermoplasty. The majority were review articles, editorials, and correspondences. Three RCTs conducted by the same group of authors were identified (AIR, AIR2, and RISA trials). RISA trial was too small (N=32), AIR trial had a 5-year follow-up, and AIR2 trial had a sham comparison group. Both AIR and AIR2 trials were selected for critical appraisal. Castro M, Rubin AS, Laviolette M, et al for the AIR2 trial Study group 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;18:116-124. See [Evidence Table](#). Cox G, Thompson NC, Rubin AS, et al for the AIR trial Study group. Asthma control during the year after bronchial thermoplasty. *N Engl J Med*. 2007;356:1327-1337 See [Evidence Table](#). Thomson NC, Rubin AS, Niven RM, et al. Long term (5 Year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. 2011;1: 8.

The use of Bronchial Thermoplasty does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
05/04/2011	Added to annual review because of Medicare changes 05/01/2014 ^{MPC} , 05/06/2014 ^{MPC} , 03/03/2015 ^{MPC} , 01/05/2016 ^{MPC} , 11/01/2016 ^{MPC} , 09/05/2017 ^{MPC} , 08/07/2018 ^{MPC}	05/06/2014

^{MDCRPC} Medical Director Clinical Review and Policy Committee
^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
04/07/2016	Removed Medicare coverage language

Codes

CPT: 31660, 31661