Priority Health

# MEDICAL POLICY No. 91577-R4

# BRONCHIAL THERMOPLASTY

| | |
|---|---|
| **Effective Date: August 23, 2023** | **Review Dates: 10/10, 10/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20, 2/21, 8/21, 8/22, 8/23** |
| **Date of Origin: October 13, 2010** | **Status: Current** |

## Summary of Changes

Change: I.A.5 – Deleted "asthma case management" and replaced with "care management".

## I. POLICY/CRITERIA

A. Bronchial thermoplasty (BT) may be performed when part of an Institutional Review Board (IRB) approved clinical trial or a registry to enable the collection of long-term data on the use of BT for asthma when all of the following are met:

1. Age 18 years or older.

2. Severe persistent asthma as defined by experiencing any of the following characteristics in the absence of asthma controller medications:

   i. Daily symptoms
   ii. Nighttime awakenings, every night
   iii. Use of rescue medication multiple times per day
   iv. Normal activities are extremely limited
   v. Impaired lung function (less than or equal to 60% predicted)
   vi. Frequent exacerbations

3. Symptom control with either:

   i. High dose inhaled corticosteroids (ICS) and long-acting beta agonists (LABA) > 3 months, or
   ii. Exacerbation requiring chronic (>3 months) oral corticosteroids.

4. Experienced at least 2 or more of the following despite taking high doses of ICS and LABA:

   i. Asthma exacerbations requiring oral systemic corticosteroids due to respiratory symptoms in the prior year.
   ii. Unscheduled physician's office visits due to respiratory symptoms in the prior year.
   iii. At least three emergency department visits for respiratory symptoms.
   iv. Hospitalizations for asthma in the preceding 12 months

5. Participation in Priority Health's care management program for at least 3 months and management by an asthma specialist for > 6 months to ensure

that patient education, environmental factors and comorbidities have been considered in the management of the patient's severe asthma.

6. Prior authorization by Priority Health.

B. Bronchial thermoplasty should be performed by clinicians who are experienced in bronchoscopy and have completed the bronchial thermoplasty training curriculum.

C. Bronchial thermoplasty is not indicated if the following applies:
   1. Presence of a pacemaker, internal defibrillator, or other implantable electronic devices.
   2. Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine, and benzodiazepines.
   3. Member previously treated with the Alair® System should not be retreated in the same area(s). No clinical data are available studying the safety and/or effectiveness of repeat treatments.

D. One complete thermoplasty procedure is performed in 3 treatment sessions with a recovery period of 3 weeks or longer between sessions. Repeat procedures, beyond the initial 3 treatments, are not medically necessary because the safety and efficacy of repeat procedures have not been studied.

## II. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required Not Applicable

*Note:* A complete thermoplasty procedure is performed in 3 treatment sessions with a recovery period of 3 weeks or longer between sessions. One prior authorization will allow for 3 treatment sessions.

## III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***

- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

## IV. DESCRIPTION

Bronchial thermoplasty is a catheter-based procedure that delivers thermal energy (radiofrequency ablation) through a bronchoscope to reduce smooth muscle mass in airway walls, thus decreasing bronchoconstriction. It is intended as an adjuvant treatment for symptom relief in patients with severe and persistent asthma despite optimal management with current care medication regimens. Approximately 10% of the asthma patient population has true refractory disease that cannot be well controlled despite adherence to treatment.

Bronchial thermoplasty is not a cure for asthma, nor will it obviate the need for continued medical management of the disease.

On April 27, 2010, the Food and Drug Administration (FDA) approved a premarket approval (PMA) application for the Alair System. The Alair System for bronchial thermoplasty is indicated for use in adult patients with severe and persistent asthma not well controlled with inhaled corticosteroids and long-acting beta agonist medications.

There have been 3 randomized controlled trial (RCT): The Research in Severe Asthma (RISA), Asthma Intervention Research Trial (AIR), and Asthma Intervention Research 2 (AIR 2). 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 United States. 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 quality-of-life (QOL) score. 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 post-treatment period. 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.

The FDA required a 5-year post-approval study of the device to study its long-term safety and effectiveness of the Alair System. The manufacture agreed to follow many of the patients who were enrolled in the clinical trial and enroll 300 new patients at several medical centers across the United States. 168 patients from the Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma (PAS2) reached three years of follow-up and were compared with 165 patients from AIR2 who also had three years of follow-up. The primary outcome was comparing the incidence of severe exacerbation in each trial. In the 12 months before treatment, 74.2% of patients from PAS2 experienced severe exacerbations, which decreased significantly during the third year of follow-up to 39.9% ($p<0.001$). A similar reduction was observed in AIR2 patients, with the incidence of severe exacerbations decreasing 36.8%. Similar decreases in emergency department visits occurred in both groups when year three was compared with the 12 months before treatment (PAS2, 55% reduction; AIR2, 72.3% reduction; $p<0.001$); the incidence of hospitalization also decreased for both groups. In the first and second years after treatment, the incidence of hospitalization in PAS2 decreased to 14.4% and 12.7%, respectively; the incidence of emergency department visits decreased to 18.3% in the first year and 13.5% in the second year after treatment.

A 10-year follow-up on the three RCT aimed to investigate the efficacy and safety of bronchial thermoplasty as a long-acting therapeutic option for patients with Asthma. The BT10+ study showed that participants treated with bronchial thermoplasty had sustainable improvements in severe exacerbations. However, participants in the control group also had decreases in severe exacerbations, hospital emergency department visits, and admissions to hospital.

Currently, both the National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) and the National Asthma Education and Prevention Program only recommend BT in the context of a clinical trial or clinical registry.

Priority Health's Technology Assessment Committee reviewed Bronchial Thermoplasty in September 2010 & December 2011; this policy is based on recommendations of the committee.

## V. CODING INFORMATION

**ICD-10 Codes**: that *may* apply:

J44.1 Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9 Chronic obstructive pulmonary disease, unspecified
J45.50 Severe persistent asthma, uncomplicated
J45.51 Severe persistent asthma with (acute) exacerbation
J45.52 Severe persistent asthma with status asthmaticus
J45.901 Unspecified asthma with (acute) exacerbation
J45.902 Unspecified asthma with status asthmaticus
J45.909 Unspecified asthma, uncomplicated

**CPT/HCPCS Codes:**

31660 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

**Not Covered:**

0781T Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi
0782T Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus

## VI. REFERENCES


1. American Thoracic Society. Proceedings of the ATS Workshop on Refractory Asthma Current Understanding, Recommendations, and Unanswered Questions. American Journal of Respiratory and Critical Care Medicine;162 (6)l: pp 2341–2351.
2. Castro, Rubin, Laviolette, et. al. Effectiveness and Safety of Bronchial Thermoplasty in the Treatment of Severe Asthma: A multi-center, randomized, double-blind, sham-controlled clinical trial, Am J Respir Crit Care, 2010; 181: 116-124,
3. Castro, M. et.al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. Annals of Allergy, Asthma & Immunology.;107, July 2011: 65-70.
4. Cigna. Medical Coverage Policy (#0502). Bronchial Thermoplasty. Available at https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0502_coveragepositioncriteria_bronchial_thermoplasty.pdf (Accessed June 22, 2023).
5. Chaudhuri R, Rubin A, Sumino K, Lapa E Silva JR et al. BT10+ Study Group. Safety and effectiveness of bronchial thermoplasty after 10 years in patients with persistent asthma (BT10+): a follow-up of three randomised controlled trials. Lancet Respir Med. 2021 May;9(5):457-466.

6. Cloutier MM, Dixon AE, Krishnan JA, Lemanske RF Jr, Pace W, Schatz M. Managing Asthma in Adolescents and Adults: 2020 Asthma Guideline Update from the National Asthma Education and Prevention Program. JAMA. 2020 Dec 8;324(22):2301-2317.
7. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, Blake KV, Brooks EG, Bryant-Stephens T, DiMango E, Dixon AE, Elward KS, Hartert T, Krishnan JA, Lemanske RF Jr, Ouellette DR, Pace WD, Schatz M, Skolnik NS, Stout JW, Teach SJ, Umscheid CA, Walsh CG. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270.
8. Hayes, Inc. The Alair® System for Bronchial Thermoplasty, July 13, 2010, October 20, 2010 & September 25, 2013. Archived November 3, 2010.
9. National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program. Expert Panel Report 3: Guideline for Diagnosis and Management of Asthma. 2007. NIH Publication No. 07-4051. Bethesda, MD.
10. Pavord, ID et al. Research in Severe Asthma Trial Study Group. Safety of bronchial thermoplasty in patients with severe refractory asthma. Ann Allergy Asthma Immunol. 2013 Nov; 111(5):402-7.
11. Wechsler, M., Laviolettem M., Rubin, AS. et.al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. The Journal of Allergy and Clinical Immunology, 03 September 2013 (10.1016/j.jaci.2013.08.009).