Molina Clinical Policy
Bronchial Thermoplasty
Policy No. 171

Last Approval: 8/11/2021
Next Review Due By: August 2022

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Bronchial thermoplasty is a minimally invasive treatment that uses thermal energy (radiofrequency ablation) to weaken and partially destroy the smooth muscle in the lungs that constricts the airway during asthma attacks. This procedure is intended for treatment of severe, persistent asthma in patients who are age 18 years or older and with asthma that has not been well controlled by long-acting bronchodilators or glucocorticoids.[3] The procedure generally involves three separate bronchoscopies under moderate sedation about three weeks apart. A radiofrequency controller and a specialized catheter are used to administer thermal energy (target tissue temperature 65˚C) to the airway walls. All reachable airways distal to the mainstem bronchus that are 3 to 10 mm in diameter are treated once, except those in the right middle lobe, which are left untreated due to difficulty with access.[31 32]

Regulatory Status

The Alair Bronchial Thermoplasty System (Boston Scientific Corp.) is regulated via the Premarket Approval (PMA) process as a Class III (high-risk) device and is subject to the most stringent regulations enforced by the FDA. The FDA has classified it as a bronchial thermoplasty system and it received FDA approval on April 27, 2010.[2]

COVERAGE POLICY

Bronchial thermoplasty is considered **experimental, investigational or unproven** for the treatment of asthma due to insufficient evidence in peer-reviewed medical literature that have not established safety, efficacy and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

A small body of low-quality evidence suggests that during the first year after thermoplasty, benefits were observed, including improved quality of life (QOL), symptom relief, reduced medication use, and reductions in emergency department (ED) visits. Bronchial thermoplasty did not reduce hospitalizations following treatment and there was no evidence of improved lung function (e.g., forced expiratory volume in 1 second [FEV1]). Although preliminary evidence suggests that this treatment poses little long-term safety risk, there is insufficient evidence concerning the long-term safety and efficacy of bronchial thermoplasty. A summary of the evidence is provided below.

Three randomized controlled trials (RCTs) have evaluated the Alair Bronchial Thermoplasty System for treatment of severe asthma. [5 6 7] Although all of these studies were RCTs, one study enrolled less than 50 patients [7] and two studies did not involve blinding or placebo controls. [6 7] All of the reviewed studies evaluated thermoplasty as an adjunct to continued drug therapy for asthma using outcome measures, including respiratory parameters, medication usage, exacerbations of asthma, hospital visits, and assessments of quality of life. The initial reports of the RCTs involved only 1 year of follow-up; however, subsequent reports for two of the RCTs extended this follow-up to 2 or 5 years for patients who underwent Thermoplasty [4 8] and one of these extensions included a subset of control group patients with 3 years follow-up. [8] All of the studies were supported by the device manufacturer and performed in part by investigators who had financial relationships with the device manufacturer.[5 6 7]

The largest available controlled study of thermoplasty for severe asthma was the Asthma Intervention Research (AIR2) trial that randomized 190 patients to thermoplasty and 98 patients to placebo treatment.[5] Throughout the study, all patients continued drug therapy with no intentional or directed changes in medication use. At 1 year follow-up, the thermoplasty group had meaningful improvements compared with the control group for the following measures: severe exacerbations (0.48 versus 0.70 per patient annually, PPS=0.96), emergency department visits (0.07 versus 0.43 per patient annually, PPS>0.99), and days lost from work, school, or other activities due to asthma (1.3 versus 3.9 per year, PPS=0.99). In addition, the thermoplasty group had meaningful improvements in mean ± standard deviation (SD) Asthma Quality of Life Questionnaire (AQLQ) scores (1.4 ± 1.1 versus 1.2 ± 1.2, PPS=0.96); however, the degree of improvement in this measure (difference = 0.2) was much smaller than the improvement in the control group (+1.2), which can presumably be attributed to a placebo effect. Despite these improvements, no meaningful differences were noted between the thermoplasty group and the control group in mean respiratory parameters, total symptom score, symptom-free days, rescue medication use, unscheduled physician visits, hospitalizations, or the Asthma Control Questionnaire (ACQ) scores at 1 year follow-up. [5] An additional year of uncontrolled follow-up of the thermoplasty group evaluated with traditional statistical tools showed no statistically significant differences within this group between 1 year and 2 years follow-up in severe exacerbations, asthma symptoms, emergency department visits or hospitalizations follow-up. [4]

Another RCT that enrolled 109 patients who had severe, persistent asthma found improvements similar to those reported above despite differences in study design.[6] This trial was not blinded or placebo controlled and most of the outcomes were measured after attempted withdrawal of patients from long-acting b2-agonist (LABA) use. At 1 year follow-up, compared with the control group, thermoplasty was associated with statistically significant improvements in mean change in the following measures: AQLQ (higher score better) (+1.3 versus +0.6, P<0.005), ACQ (lower score better) (–1.2 versus –0.5, P<0.005), symptom free days (+41% versus +17%, P<0.01), symptom scores (lower score better) (–1.9 versus –0.7, P<0.05), rescue bronchodilator use (–8.9 versus –1.2 puffs per week, P<0.05), morning peak expiratory flow (+39 versus +9 liters per minute, P<0.005), mild exacerbations without LABA (–0.16 versus +0.04, P<0.01), and mild exacerbations with LABA (–0.17 versus +0.03, P<0.05). In contrast, at 1 year follow-up, no significant differences were seen between the thermoplasty group and the control group in severe exacerbations, airway responsiveness, or forced expiratory volume in 1 second (FEV1).[6] A second report of this study extended follow-up to 5 years for 45 (82%) thermoplasty group patients and to 3 years for 24 (44%) control group patients.[8] Thermoplasty was not associated with any serious long-term adverse events and at 3 years follow-up, airway responsiveness measured based on doublings of methacholine dose giving a 20% decrease in FEV1 increased 1.3 doublings for the thermoplasty group versus a decrease of 0.4 doublings for the control group (P<0.05). However, at 3 years follow-up, there were no significant differences between the thermoplasty group and the control group in other respiratory parameters, oral glucocorticoid use, worsening of asthma, emergency department visits, or hospitalizations.[8] The apparent loss of benefits of thermoplasty during longer follow-up may indicate loss of effectiveness over time or may be an artifact of selective dropping out of control group patients who have the most poorly controlled asthma.

In the Research In Severe Asthma (RISA) trial 32 patients with severe asthma (prebronchodilator FEV1 ≥50 percent of predicted) were randomly assigned to BT or control (without sham procedure) but investigators were not blinded. [7] This trial was not blinded or placebo controlled and patients underwent attempted weaning from oral and inhaled glucocorticoids during weeks 22 to 36 of the study and maintenance of reduced steroid use during weeks 37 to 52 of the study. Compared with the control group at 22 weeks follow-up (before steroid weaning), thermoplasty was associated with statistically significant improvements in mean change in the following measures: FEV1 (+15% versus –1%, P<0.05), AQLQ (higher score better) (+1.2 versus +0.2, P<0.05), ACQ (lower score better) (–1.0 versus –0.1, P<0.05), and rescue bronchodilator use (–27% versus –2%, P<0.05). Except for FEV1, improvements in these measures remained statistically significant at 52 weeks follow-up, after reduction of steroid dosages. Compared with the control group at 52

weeks, thermoplasty was associated with statistically significant improvements in mean AQLQ (higher score better) (+1.5 versus +0.4, P<0.05), mean ACQ (lower score better) (–1.0 versus –0.2, P<0.05), and mean rescue bronchodilator use (–26% versus –6%, P<0.05).[3]

In a follow-up of 162 patients who underwent BT in the AIR2 trial, the effectiveness and safety of BT was evaluated in a prospective study 5 years after therapy.[3] Outcomes assessed after BT included severe exacerbations, adverse events, health care use, spirometric data, and high-resolution computed tomographic scans. The proportion of subjects experiencing severe exacerbations and emergency department (ED) visits and the rates of events in each of years 1 to 5 remained low and were less than those observed in the 12 months before BT treatment (average 5-year reduction in proportions: 44% for exacerbations and 78% for ED visits). Respiratory adverse events and respiratory-related hospitalizations remained unchanged in years 2 through 5 compared with the first year after BT. Prebronchodilator FEV1 values remained stable between years 1 and 5 after BT, despite a 18% reduction in average daily inhaled corticosteroid dose. High-resolution computed tomographic scans from baseline to 5 years after BT showed no structural abnormalities that could be attributed to BT. However, there was no follow up of the control group, making comparisons difficult.[3]

A 2014 **Cochrane review** was published on the efficacy and safety of bronchial thermoplasty in adults with bronchial asthma. Three trials (429 participants) were included (two trials compared bronchial thermoplasty vs medical management and the other compared bronchial thermoplasty vs a sham intervention). The results from two trials showed a lower rate of exacerbation after 12 months of treatment for participants who underwent bronchial thermoplasty. The trial with sham intervention showed a significant reduction in the proportion of participants visiting the emergency department for respiratory symptoms, from 15.3% on sham treatment to 8.4% over 12 months following thermoplasty. The trials showed no significant improvement in pulmonary function parameters (with the exception of a greater increase in morning peak expiratory flow (PEF) in one trial). Treated participants who underwent bronchial thermoplasty had a greater risk of hospitalization for respiratory adverse events during the treatment period (3 trials, 429 participants; risk ratio 3.50, 95% CI 1.26 to 9.68; high-quality evidence), which represents an absolute increase from 2% to 8% (95% CI 3% to 23%) over the treatment period. This means that six of 100 participants treated with thermoplasty (95% CI 1 to 21) would require an additional hospitalization over the treatment period. No significant difference in the risk of hospitalization was noted at the end of the treatment period. The review concluded that bronchial thermoplasty for patients with moderate to severe asthma provides a modest clinical benefit in quality of life and lower rates of asthma exacerbation, but no significant difference in asthma control scores. [9]

Professional Society Guidelines

American College of Allergy, Asthma and Immunology (ACAAI). Guidelines published in 2015 indicate that bronchial thermoplasty is a well-studied treatment for patients with very severe asthma who continue to be symptomatic despite maximal medical treatment including steroids, long-acting beta agonists (LABAs), long-acting muscarinic agents (LAMAs), leukotriene antagonists and biologics. The device to deliver this therapy is FDA approved. The scientific literature supports bronchial thermoplasty as a therapeutic consideration for some carefully chosen patients with severe asthma. Carefully selected patients with severe, persistent asthma who have persistent burden of disease, asthma exacerbations, emergency department visits or hospitalizations despite maximal medical treatment may benefit from this procedure. Therefore, ACAAI recommends that insurers provide coverage bronchial thermoplasty for those adult patients who meet the stringent requirements.[29]

American College of Chest Physicians (CHEST). A Coverage and Payment for Bronchial Thermoplasty for Severe Persistent Asthma document published in 2014 notes that bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental. It should be noted that this document is not a guideline.[30]

British Thoracic Society (BTS) & Scottish Intercollegiate Guidelines Network. Guidelines prepared jointly in 2019 indicate that: “Bronchial thermoplasty may be considered for the treatment of adult patients who have poorly controlled asthma despite optimal therapy. Patients being considered for bronchial thermoplasty should be assessed to confirm the diagnosis of asthma, that uncontrolled asthma is the cause of their ongoing symptoms, and that they are adherent with current treatment.” [25]

Global Initiative for Asthma (GINA). Updated guidelines (2020) indicate that "bronchial thermoplasty is a potential treatment option for adult patients whose asthma remains uncontrolled despite optimized therapeutic regimes and referral to an asthma specialty center. (Evidence level B)" [27]

National Institute for Health and Clinical Excellence (NICE): Updated guidelines (2018) indicate that "Current evidence on the safety and efficacy of bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. The procedure should only be done by a multidisciplinary team in specialist centres with on-site access to intensive care. It should only be done by clinicians with training in the procedure and experience in managing severe asthma. [28]

SUPPLEMENTAL INFORMATION

N/A

CODING & BILLING INFORMATION

Covered CPT Codes

CPT	Description
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

Covered HCPCS Codes

	Any / All

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/11/2021	Policy reviewed, no new randomized clinical trials or meta-analysis reports were found in the literature to change criteria or recommendation. This procedure remains experimental, investigational and unproven as a treatment for asthma. Updated references, guideline sections
6/17/2020	Policy reviewed, no changes in coverage criteria. IRO Peer Review. 4/2020. Policy reviewed by practicing physician board certified in Internal Medicine, Pulmonary Disease, Critical Care.
6/19/2019	Policy reviewed, no changes in coverage criteria
7/10/2018	Policy reviewed, no changes in coverage criteria. The following sections were updated: Summary of medical evidence, guidelines and references.
3/30/2017	Policy reviewed, no changes in coverage criteria.
6/15/2016	Policy reviewed, no changes in coverage criteria.
12/16/2015	Policy reviewed, no changes in coverage criteria.
6/12/2014	New Policy. IRO Peer Review 5/4/2014: Policy reviewed by practicing physician board-certified in Internal Medicine, Pulmonary Disease, Critical Care, Sleep Medicine

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Government Agencies

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) Search [search: asthma, bronchial thermoplasty]. Accessed at: CMS

2. Center for Devices and Radiological Health (CDRH). Premarket Approval (PMA) Database [search: P080032]. Alair Bronchial Thermoplasty System. April 27, 2010. Food and Drug Administration [website]. Available at: FDA

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2020 Literature Update

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National and Specialty Organizations

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APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Washington
MCP to be used for determination of medical necessity in conjunction with the HTA Final Evidence Report (4/14/2006): Bronchial Thermoplasty for Asthma.