Molina Clinical Policy
Bronchial Thermoplasty: Policy No. 171

Last Approval: 08/14/2024
Next Review Due By: August 2025

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 exacerbations. This procedure is intended for the 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 (Fong et al. 2023). 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 (Wenzel 2023; Hayes 2022).

Regulatory Status

The Alair Bronchial Thermoplasty System (Boston Scientific Corp.) received Premarket Approval on April 27, 2010, as a Class III (high-risk) device and is subject to stringent FDA regulations (FDA 2010). Additional supplements may be found by searching the premarket approval database with product code “OOY.”

COVERAGE POLICY

Bronchial thermoplasty is considered **experimental, investigational, or unproven** for the treatment of asthma and other indications (e.g., chronic obstructive pulmonary disease) 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 benefits were observed during the first year following thermoplasty. This included: improved quality of life, symptom relief, reduced medication use, and reductions in emergency department 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 [FEV_1]). While preliminary evidence suggests that this treatment poses little long-term safety risk, there is insufficient evidence concerning the long-term safety and efficacy.

Bronchial Thermoplasty for Asthma

Fong et al. (2023) completed a systematic review and meta-analysis comparing bronchial thermoplasty to biological therapies in the treatment of severe asthma. There were 29 randomized controlled trials (RCTs) included with a total of 15,547 participants. The six outcomes analyzed were the Asthma Control Questionnaire, the Asthma Quality of Life Questionnaire, the number of patients experiencing ≥ 1 asthma exacerbation, the annualized exacerbation rate ratio, oral corticosteroid dose reduction, and morning peak expiratory flow rate. Participants treated with bronchial thermoplasty had a lower rate of asthma exacerbations when compared to biological therapies, though the difference was not significant. However, there were significant improvements in the bronchial thermoplasty group for the Asthma Control Questionnaire, the Asthma Quality of Life Questionnaire, oral corticosteroid dose reduction, and morning peak flow rates when compared to the biological therapies group. Annualized exacerbation rate ratios were similar among both groups.

Goorsenberg et al. (2021) completed an investigator-initiated, international multicenter RCT to assess the effects of bronchial thermoplasty on airway smooth muscle mass and to identify patient characteristics that correlate with a response to bronchial thermoplasty. A total of 40 patients between the ages of 18-65 years were included in the study and were randomized to immediate (n=20) or delayed (n=20) bronchial thermoplasty treatment. Those undergoing delayed treatment completed the first bronchial thermoplasty six months after being enrolled in the study. Baseline clinical data including a bronchoscopy to determine airway smooth muscle mass was obtained prior to randomization. Patients also had to demonstrate bronchial hyperresponsiveness on a methacholine or histamine challenge and have a full pulmonary function test within 5 years of the procedure. Exclusion criteria included negative methacholine or histamine challenge, prebronchodilator FEV_1 < 50% of predicted or < 1.2L, five or more hospitalizations or more than one intensive care unit admission requiring intubation in the year preceding the study, oral corticosteroid maintenance therapy of more than 20mg per day, asthma exacerbation or respiratory tract infection in the 4 weeks prior to the initial procedure, inability to undergo multiple bronchoscopies, or comorbidities. Bronchial thermoplasty treatment sessions were completed on all lung lobes except the right middle lobe and there was a 3-week interval between procedure sessions. Patients were treated with 50mg of prednisolone 3 days before the session, during the session, and 1 day after the session. Results showed airway smooth muscle mass decreased by 53% from 8.75% to 4.14% in the immediate treatment group while the delayed group did not demonstrate a decrease in airway smooth muscle mass following 6 months of standard care. Overall airway smooth muscle mass size for the entire group decreased from 8.6% to 4.02% following bronchial thermoplasty. Improvements were noted in Asthma Control Questionnaire and Asthma Quality of Life Questionnaire scores following bronchial thermoplasty. In addition, the exacerbation rate per 6 months decreased from 1.5 before bronchial thermoplasty to zero after bronchial thermoplasty.

Long Term Follow-up

Hatch et al. (2023) completed a study of 51 participants to determine long-term outcomes at 5-years following bronchial thermoplasty. Participants were recruited using registry data from the Australian Bronchial Thermoplasty Register. All patients underwent “extensive evaluation, including multidisciplinary assessment [and were] considered compliant with high-dose inhaled steroids and two long-acting bronchodilators, plus, if suitable, additional treatment such as monoclonal antibody therapy” prior to bronchial thermoplasty. Baseline data collected included Asthma Control Questionnaire scores, lung function testing (spirometry and diffusing capacity), biomarker measurement, and high-resolution chest computed tomography scans. Those participating in the 5-year follow-up study were asked to complete a clinical assessment that included the same data collected at baseline along with a medication review and an interview. High-resolution chest computed tomography scans were interpreted using the modified Reiff score for bronchiectasis and the BRICS CT scoring system for bronchiectasis. Efficacy was measured by comparing the baseline and 5-year follow-up measures of Asthma Control Questionnaire scores, exacerbation frequency, medication requirement, and prebronchodilator FEV_1 percent predicted. Median age at baseline was 59.0±11.8 years. The baseline characteristics of all participants included: a) a mean Asthma Control Questionnaire score of 3.0±1.0, b) mean exacerbation frequency requiring oral corticosteroid in the 12 months prior to bronchial thermoplasty of 3.9±3.6 events, c) 27 participants were treated with maintenance oral prednisolone at baseline, d) a mean prebronchodilator FEV_1 of 55.5±18.8% of predicted with an average improvement of 16.8±14.8% following administration of 400 µg salbutamol, e) a mean diffusing capacity for carbon monoxide of 96.3±18.8% of predicted, f) a mean short-acting beta agonist usage of 8.9±6.4 puffs per day, and g) 89% of participants demonstrated a high TH2 high asthma phenotype. The mean total number of thermoplasty treatments delivered for each participant was 202±57. The characteristics of all participants at 5-year follow-up were: a) a mean Asthma Control Questionnaire score of 1.8±1.1 ($p < 0.001$), b) mean exacerbation frequency per year of 1.0±1.6 ($p < 0.001$), c) 15 participants required oral corticosteroid maintenance

therapy, d) a mean predicted FEV_1 of 58.7±19.9% (p = 0.146), and e) a mean short-acting beta agonist usage of 4.0±5.3 puffs per day (p < 0.001). Approximately 47 participants completed the high-resolution chest computed tomography scans with 24 participants receiving a Reiff score of zero and "the remaining 23 patients showed some features suggesting localized radiological bronchiectasis." Of note, "the highest [Reiff score] was 15, but this patient also scored 15 on his baseline scan." The mean BRICS CT score post-bronchial thermoplasty was 0.5±0.9 out of 5 compared to a 5-year follow-up of 0.9±1.2 (p < 0.001). Researchers noted that there was an overall reduction of 75% in exacerbation frequency that was maintained from 6-months to 5-years post-treatment and those with more severe asthma tended to benefit the most from bronchial thermoplasty. Researchers also noted that the long-term results of this study are for patients that would qualify for bronchial thermoplasty while the long-term results of the BT10+ study (Chaudhuri et al. 2021) represent patients that may no longer qualify for bronchial thermoplasty due to having less severe asthma that does not meet the current "qualification standards" for receiving bronchial thermoplasty.

Chaudhuri et al. (2021) completed the BT10+ study which was a follow-up study of participants previously enrolled in the AIR, RISA, and AIR2 trials who had 10 or more years of follow-up following bronchial thermoplasty. A total of 192 participants were included in the study with 136 of those receiving bronchial thermoplasty and 56 receiving a sham or control treatment. The primary outcome measured was the proportion of participants experiencing severe asthma exacerbations at the 1- and 5-year mark following bronchial thermoplasty and the month prior to the BT10+ follow-up visit. Those that had undergone bronchial thermoplasty had similar rates of severe asthma exacerbations at 1-year (n=33/135) following bronchial thermoplasty, at 5 years (n=28/130) following bronchial thermoplasty, and at the BT10+ follow-up visit (n=34/136). Quality of life measures and spirometry were similar at all follow-up points. In addition, those in the AIR2 trial (n=97) received pulmonary high-resolution computed tomography scans. Approximately 13 of 97 participants in the AIR2 trial had bronchiectasis with 6 of those developing bronchiectasis after receiving bronchial thermoplasty.

Bronchial Thermoplasty for Chronic Obstructive Pulmonary Disease (COPD)

Wang et al. (2023) completed a randomized pilot study to determine the safety and efficacy of bronchial thermoplasty for the treatment of moderate-to-severe COPD. A total of 57 participants were included in the study with 29 being randomized to the control group and 28 randomized to the intervention group. Both groups were treated with conventional medical therapy during the stable COPD period. The intervention group received treatment with bronchial thermoplasty in addition to the conventional medical therapy. For the year prior to the study, "all patients received high doses of [inhaled corticosteroids] in the past year and were using [long-acting bronchodilator and muscarinic agents]." Inclusion criteria included a) age between 40 and 75 years, b) diagnosis of COPD in accordance with GOLD guidelines for at least two years prior to the study and classification as moderate or severe COPD according to GOLD guidelines, c) ability to provide medical records related to hospitalizations for the year prior to the study, and d) ability of participant to document or state changes in their condition. Exclusion criteria included a) current acute respiratory infection, b) acute COPD exacerbation within the two weeks prior to study enrollment, c) communication disorders, d) inability to complete all three bronchial thermoplasty sessions, and e) other respiratory-related comorbidities such as asthma. Baseline characteristics for the control group were: a) mean age 66.48±9.89 years, b) body mass index 22.08±3.08, c) smoking pack-years = 30, d) years diagnosed with COPD = 10.0, e) FEV_1 = 0.93±0.47L, f) FEV_1 % predicted = 37.52±13.90%, g) FEV_1/forced vital capacity [FVC] = 49.61±15.68%, h) 6-minute walk test = 243.10±75.29m, and i) mean COPD assessment test [CAT] score = 27.93±3.45. Baseline characteristics for the intervention group were: a) mean age 68.18±6.99 years, b) body mass index 22.33±4.48, c) smoking pack-years = 40, d) years diagnosed with COPD = 10.0, e) FEV_1 = 0.88±0.34L, f) FEV_1 % predicted = 34.60±10.54%, g) FEV_1/FVC = 46.77±10.54%, h) 6-minute walk test = 254.29±49.18m, and i) mean CAT score = 27.68±4.51. The number of participants diagnosed with emphysema (control = 23, intervention = 24) and GOLD grading (grade 2, control = 5, intervention = 4; grade 3, control = 15, intervention = 15; grade 4, control = 9, intervention = 9) were similar among both groups. Mean changes from baseline at 3- and 12-month follow-ups for the control group were: a) FEV_1 0.10±0.04L and 0.11±0.11L, b) FEV_1 % predicted 3.29±1.72% and 3.77±4.98%, c) FVC 0.22±0.40 and 0.22±0.42L, d) 6-minute walk test 24.83±8.78 and 31.52±25.49m, and e) CAT score -2.76±1.50 and -3.52±1.94. Mean changes from baseline at 3- and 12-month follow-ups for the intervention group were: a) FEV_1 0.17±0.06L and 0.24±0.15L, b) FEV_1 % predicted 6.58±3.02% and 9.19±6.58%, c) FVC 0.25±0.19 and 0.34±0.27L, d) 6-minute walk test 42.79±17.53 and 78.07±36.20m, and e) CAT score -4.93±2.51 and -7.36±3.64. Researchers also compared the acute exacerbation risk between both groups. The proportion of high-risk patients with acute COPD exacerbation in the control group was 29 one year before treatment and 19 one year after treatment (p = 0.002) compared to 28 one year before treatment and 8 one year after treatment for the intervention group (p < 0.001). The number of inpatients with acute COPD exacerbation in the control group was 29 one year before treatment and 18 one year after treatment (p = 0.001) compared to 28 one year before

treatment and 8 one year after treatment for the intervention group ($p < 0.001$). Adverse events in the intervention group were limited to typical COPD symptoms (cough, increased expectoration, wheezing, chest tightness and pain, pneumonia, etc.), occurred within three weeks of intervention, and most resolved within one week of onset or with symptomatic treatment. Researchers noted that bronchial thermoplasty can "better improve lung function of COPD patients [compared to] conventional medical treatment, significantly improve life quality and reduce COPD acute exacerbation." Limitations of this study included a lack of a sham-operation group, the participants were limited to those with moderate-to-severe COPD with varying degrees of severity of emphysema, and airway biopsy samples were not collected to determine the pathological changes associated with bronchial thermoplasty.

National and Specialty Guidelines

The American College of Allergy, Asthma, and Immunology (ACAAI) guidelines were updated in 2018 and 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, long-acting muscarinic agents, leukotriene antagonists, and biologics. The device is FDA approved and 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. The ACAAI recommends that insurers provide coverage of bronchial thermoplasty for those adult patients who meet the stringent requirements.

The British Thoracic Society (BTS) Scottish Intercollegiate Guidelines Network (SIGN) (2019) published guidelines stating that bronchial thermoplasty may be considered for patients aged 18 years and over with severe, poorly controlled asthma despite optimal medical therapy.

The Global Initiative for Asthma (GINA) updated the *Global Strategy for Asthma Management and Prevention* guidelines (2024). Bronchial thermoplasty may be considered as an add-on treatment for adult patients with severe asthma. However, evidence is limited and long-term effects, including lung function, are unknown when compared with control patients. GINA recommends considering bronchial thermoplasty with registry enrollment so safety and effectiveness can be determined.

The National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group (NAEPPCC) published a 2020 update to the *Asthma Management Guidelines* with a conditional recommendation against bronchial thermoplasty for patients aged 18 and older with persistent asthma. The NAEPPCC states "Individuals ages 18 years and older with persistent asthma who place a low value on harms…and a high value on potential benefits…might consider bronchial thermoplasty." The NAEPPCC recommends those undergoing bronchial thermoplasty be enrolled in registries, ongoing clinical trials, or studies that track the long-term safety and effectiveness. Additionally, guidelines do not recommend bronchial thermoplasty "in individuals with an FEV_1 < 50-60% of predicted FEV_1."

The National Institute for Health and Clinical Excellence (NICE) (2018) guideline on *Bronchial Thermoplasty for Severe Asthma* (2018) indicates that bronchial thermoplasty may be considered for patients with severe asthma when "standard arrangements are in place for clinical governance, consent and audit". The guideline also states that the procedure should be performed when a multidisciplinary team is involved at a specialty center equipped with an intensive care unit.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	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

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 not

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

08/14/2024	Policy reviewed, no changes to coverage criteria.
08/09/2023	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and Reference sections. Removed Supplemental Information section. IRO Peer Review on June 22, 2023, and July 3, 2023, by practicing, board-certified physicians with specialties in Critical Care, Internal Medicine, and Pulmonary Disease.
08/10/2022	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence and Reference sections.
08/11/2021	Policy reviewed, no changes to coverage criteria. Updated references and Summary of Medical Evidence..
06/17/2020	Policy reviewed, no changes to coverage criteria. IRO Peer Review April, 2020. Policy reviewed by practicing physician board certified in Internal Medicine, Pulmonary Disease, Critical Care.
06/19/2019	Policy reviewed, no changes to coverage criteria.
07/10/2018	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
03/30/2017	Policy reviewed, no changes to coverage criteria.
06/15/2016	Policy reviewed, no changes to coverage criteria.
12/16/2015	Policy reviewed, no changes to coverage criteria.
06/12/2014	New Policy.

REFERENCES

1. American College of Allergy, Asthma, and Immunology (ACAAI). Statement on bronchial thermoplasty. Published January 5, 2018. Accessed June 15, 2023. https://college.acaai.org/.
2. British Thoracic Society (BTS), Scottish Intercollegiate Guidelines Network (SIGN). SIGN 158. British guideline on the management of asthma: A national clinical guideline. Published 2003. Updated July 2019. Accessed June 15, 2023. https://www.sign.ac.uk/media/1773/sign158-updated.pdf.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Accessed June 15, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
4. Chaudhuri R, Rubin A, Sumino K, et al. 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. doi: 10.1016/S2213-2600(20)30408-2. Epub 2021 Jan 29. PMID: 33524320.
5. Fong KY, Zhao JJ, Syn NL, et al. Comparing bronchial thermoplasty with biologicals for severe asthma: Systematic review and network meta-analysis. Respir Med. 2023 May 29; 216:107302. doi: 10.1016/j.rmed.2023.107302. Epub ahead of print. PMID: 37257786.
6. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Updated May 2024. Accessed June 14, 2024. https://ginasthma.org.
7. Goorsenberg AWM, d'Hooghe JNS, Srikanthan K, et al. Bronchial Thermoplasty Induced Airway Smooth Muscle Reduction and Clinical Response in Severe Asthma. The TASMA Randomized Trial. Am J Respir Crit Care Med. 2021 Jan 15;203(2):175-184. doi: 10.1164/rccm.201911-2298OC. PMID: 32721210.
8. Hatch M, Lilburn P, Scott C, et al. Safety and efficacy of bronchial thermoplasty in Australia 5 years post-procedure. Respirology. 2023 Nov;28(11):1053-1059. doi: 10.1111/resp.14568. Epub 2023 Aug 7. PMID: 37550800.
9. Hayes. Health technology assessment: Bronchial thermoplasty for treatment of asthma in adults. Published July 5, 2022. Accessed June 16, 2023. https://evidence.hayesinc.com/.
10. National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC). 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 doi: 10.1016/j.jaci.2020.10.003. Erratum in: J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530. PMID: 33280709; PMCID: PMC7924476.
11. National Institute for Health and Care Excellence (NICE). Bronchial thermoplasty for severe asthma Interventional procedures guidance [IPG635]. Published December 19, 2018. Accessed June 15, 2023. https://www.nice.org.uk/guidance/ipg635.
12. United States Food and Drug Administration (FDA). Alair bronchial thermoplasty system (P080032). Published April 27, 2010. Accessed June 11, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
13. Wenzel S. Treatment of severe asthma in adolescents and adults. Updated June 15, 2023. Accessed June 16, 2023. www.uptodate.com/.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Washington

For Medicaid reviews, consider and apply the following state-specific criteria: HTA Final Evidence Report (4/14/2006): Bronchial Thermoplasty for Asthma.