Bronchial Thermoplasty
Clinical Coverage Criteria

Description

Patients with severe, persistent asthma are managed with multiple medications that may include inhaled, orally administered, and biologic therapeutics. Some of these patients might be eligible for bronchial thermoplasty (BT), an interventional treatment option that involves the delivery of controlled radiofrequency (RF) thermal energy to the walls of accessible proximal airways with the intent of reducing excess smooth muscle tissue in the airways.

The Alair™ Bronchial Thermoplasty System (Boston Scientific Corp.) received FDA Premarket Approval (PMA) on April 27, 2010, for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists (Product Code OOY; Premarket Approval (PMA) P080032). The Alair® Bronchial Thermoplasty system remains the only FDA-approved device for the treatment of severe persistent asthma. Physicians perform three bronchoscopic procedures to different areas of the lung approximately 3 weeks apart: the lower lobe of the right lung, the lower lobe of the left lung, then both upper lobes in the final procedure. In each procedure, the physician performs about 45 to 60 smooth muscle ablations heating the airway wall to about 150ºF for 10 seconds. Each procedure usually takes under an hour. Sedation for bronchial thermoplasty typically involves a combination of moderate or deep sedation and local anesthesia.

In 2022, Boston Scientific Corporation announced the discontinuation of sales of the Alair Bronchial thermoplasty System globally. Alair Bronchial Thermoplasty Catheters and Accessory Kits will be sold through December 31, 2024. Alair Bronchial Thermoplasty Controllers will be serviced through December 31, 2025. Bronchial thermoplasty will remain available as long as catheter stock lasts (Noble et al., 2024).

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Bronchial Thermoplasty requires prior authorization. Requests must be supported by documentation in the treating provider(s) medical records.

Fallon Health Clinical Coverage Criteria

Fallon Health considers bronchial thermoplasty medically necessary when all of the following criteria are met:

1. The member must be 18 years of age or older.

2. The member has been diagnosed with severe persistent asthma with daily symptoms resulting in the use of a rescue inhaler such as the below:
    - Wheezing, coughing, chest tightness, and shortness of breath.
    - Persistent nighttime symptoms.
3. The severe symptoms are limiting the member's daily physical activities.
4. The member's symptoms have been treated and medically managed by an Asthma Specialist for a minimum of 6 months.
5. Symptomatic despite high dose inhaled corticosteroids and long-acting-beta-agonists for a minimum of 3 months, with two or more asthma exacerbations in the past 12 months. The exacerbations required oral/systemic corticosteroids or hospitalization.
6. The member is a non-smoker for at least 1 year and if former smoker, less than 10 pack years total smoking history.
7. The member does not have a contraindication to bronchial thermoplasty:
    - Presence of a pacemaker, internal defibrillator or other implantable electronic device.
    - Known sensitivity to medications required to perform bronchoscopy, including lidocaine, atropine and benzodiazepines.
    - Patients previously treated with bronchial thermoplasty should not be retreated. There is no clinical data on the safety and/or effectiveness of repeat treatments.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for bronchial thermoplasty. Medicare does not have a National Coverage Determination (NCD) for bronchial thermoplasty. National Government Services, Inc. does not have a Local Coverage Determination (LCD) for bronchial thermoplasty at this time (Medicare Coverage Database search 02/20/2025). Coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for bronchial thermoplasty, therefore, Fallon Health Clinical Coverage Criteria are applicable (MassHealth website search 02/20/2025).

Exclusions

- Any use of bronchial thermoplasty other than outlined above.

Summary of Evidence

Randomized Controlled Trials

Three multicenter, randomized controlled trials (RCTs) have examined the safety and effectiveness of bronchial thermoplasty (BT), using the Alair™ Bronchial Thermoplasty System, in the treatment of severe persistent asthma. Two studies, Research In Severe Asthma (RISA) (Pavord et al., 2007) and Asthma Intervention Research (AIR) (Cox et al., 2007) compared BT to standard drug therapy. The third study, Asthma Intervention Research 2 (AIR2) (Castro et al., 2010) compared BT to sham bronchoscopy to mitigate an expected placebo effect.

The FDA PMA approval for Alair™ Bronchial Thermoplasty System (PMA P080032) was based on the safety and effectiveness results from the AIR2 pivotal trial. The FDA required the manufacturer to conduct two post-marketing approval studies: AIR2 Extension Study to Demonstrate Longer-term (> 1 Year) Durability of Effectiveness (PAS1) (Wechsler et al., 2013) evaluated durability of effectiveness out to 5 years in participants who were in the follow-up phase from AIR2 and Bronchial Thermoplasty in Severe Persistent Asthma (PAS2) (Chupp et al., 2022) was an open label, single-arm study designed to demonstrate durability of treatment effect and evaluate safety out to 5 years.

Research In Severe Asthma (RISA)

The purpose of this study is to evaluate the safety and efficacy of the Alair System for the treatment of severe persistent asthma.[1] Results of the RISA study were published by Pavord et al., 2007. Eligibility criteria for the RISA study (Clinicaltrials.gov NCT00214539) included:

- Adult aged 18 to 65 years
- Asthma requiring regular maintenance medication that included high-dose inhaled corticosteroids (ICS) (> 750 µg fluticasone propionate per day or equivalent) and a long acting β2 agonist (LABA) (at least 100 µg salmeterol per day or equivalent), with or without daily oral corticosteroids (OCS) (≤ 30 mg/day prednisone) leukotriene modifiers, theophylline or other asthma control drugs.
- Pre-bronchodilator forced expiratory volume in one second (FEV_1) ≥50% predicted
- Symptomatic despite medication with high dose ICS and LABA
- Demonstrated airway hyper-responsiveness by challenge with methacholine or reversible bronchoconstriction during prior 12 months
- Abstinence from smoking for 1 year or greater and past smoking history of less than 10 pack years.

After a 2-week run-in period, 34 subjects were randomized (1:1) to either the BT group or the control group. All subjects maintained baseline asthma medications. Baseline parameters were similar between groups except for symptom score (5.6 for the BT group and 3.4 for control group, p = 0.02). Two subjects in the BT group withdrew prior to treatment initiation. The remaining 32 subjects completed the study. All subjects met the Global Initiative for Asthma (GINA) criteria for severe persistent asthma (GINA, 2004). Subjects assigned to the BT group underwent three bronchoscopy procedures performed with the use of the Alair™ System at intervals of approximately 3 weeks. The control group had office visits at the same intervals. All subjects were given 50 mg prednisone/day for 5 days, beginning 3 days before each treatment or control visit. After the treatment period, subjects entered a 16-week steroid stable phase (Weeks 6–22), followed by a 14-week steroid wean phase (Weeks 22–36), and a 16-week reduced steroid phase (Weeks 36–52). Investigators were not blinded to treatment.

The primary outcome measure in the RISA study was respiratory adverse events (AEs) per subject reported during the treatment period and during the post-treatment period. AEs were designated as respiratory- or non–respiratory-related. In addition, an adverse event could also be classified as a serious adverse event (SAE). SAEs were predefined. Secondary outcome measures included change in OCS and ICS, use of rescue medication, morning and evening peak expiratory flow (PEF), FEV1, PC20 (provocative concentration causing a 20% fall in FEV_1), asthma symptom score, symptom-free days, Asthma Quality of Life Questionnaire (AQLQ) score and Asthma Control Questionnaire (ACQ) score. Patients used diaries to record asthma symptoms morning and evening PEF and daily medication use.

During the treatment period, there were seven hospitalizations for respiratory adverse events involving four subjects in the BT group and none in the control group. Five of the seven hospitalizations in the BT group were for exacerbations of asthma and two were for partial collapse of a lower lobe of the lung. In one case, a left lower lobe segment collapsed 2 days after treatment of the same area and the lung segment reinflated after physiotherapy plus standard medical therapy. In the other case, the lung segment collapse occurred the day after treatment of the area and was due to a mucus plug; aspiration of the mucus plug resulted in reinflation of the lung segment. The median length of stay for the hospitalizations in the BT group during this period was 2 days. In addition, two subjects in the BT group had five severe respiratory adverse events (chest infection, increased wheeze, cough, shortness of breath on exertion) and two subjects in the control group had two severe respiratory adverse events (dyspnea, chest infection) that were medically treated and did not result in hospitalization. In the post-treatment period, five hospitalizations occurred in three subjects in the BT group and four hospitalizations

[1] All subjects met the 2004 Global Initiative for Asthma (GINA) criteria for severe persistent asthma (Pavord et al., 2007).

occurred in one subject in the control group. This difference was not statistically significant (p = 0.32). No BT subjects required intubation or treatment in the intensive care unit (ICU); one control subject had an exacerbation on Day 42 that resulted in management in the ICU (respiratory failure). In addition, in the post-treatment period, two subjects in the BT group had five severe respiratory adverse events (increased wheeze, chest tightness, increased breathlessness, nocturnal wheeze, and chest infection) and one subject in the control group had one severe respiratory adverse event (flu-like syndrome), all of which were medically treated and did not result in hospitalization. No statistical analysis was done that compared SAEs in the two groups.

At 22 weeks, BT subjects had significant improvements in rescue bronchodilator use from baseline compared with the control group (- 26.6 ± 40.1 vs. –1.5 ± 11.7 puffs/7 d, $p < 0.05$). There were significant improvements in the percentage change from baseline in the prebronchodilator FEV_1% predicted in the BT group compared to the control group at 22 weeks (14.9 ± 17.4 vs. - 0.94 ± 22.3%, p = 0.04), Significant improvements from baseline to 22 weeks were also observed in AQLQ and ACQ scores: in the BT group, AQLQ scores improved by 1.21 ± 1.05 compared with 0.15 ± 0.75 for the control group (p = 0.003), and ACQ scores improved (noted by a decrease in the score) by 21.04 ± 1.03 versus 20.13 ± 1.00 in the control group (p = 0.02).

At 52 weeks, BT subjects compared with control subjects continued to show a significantly better improvement in rescue bronchodilator use (- 25.6 ± 31.2 vs. - 6.1 ± 12.4 puffs/7 d, $p < 0.05$), AQLQ scores (1.53 ± 0.79 vs. 0.42 ± 0.82, $p < 0.001$;), and ACQ scores (- 0.99 ± 0.83 vs. - 0.22 ± 0.78, p = 0.01). There were no significant differences between groups in the change from baseline and the end of this reduced steroid phase in the other efficacy measures.

Asthma Intervention Research (AIR)
The purpose of this study is to evaluate the safety and efficacy of the Alair System for the treatment of severe persistent asthma. Results of the AIR study were published by Cox et al., 2007. Eligibility for the AIR study (Cinicaltrials.gov NCT00214526) included:

- Adult aged 18 to 65 years
- Moderate or severe persistent asthma[2] requiring regular maintenance medication that includes ICS (at least 200 µg beclomethasone per day or equivalent) AND LABA (at least 100 mg salmeterol per day or equivalent)
- Pre-bronchodilator FEV_1 of 60-85% of the predicted value (patients stabilized on ICS and LABA)
- Airway hyperresponsiveness, defined by a provocative concentration of methacholine required to lower the FEV_1 by 20% (PC20) of less than 8 mg per milliliter
- Non-smoker for 1 year or greater (if former smoker, less than 10 pack years total smoking history)

One hundred and twelve (112) subjects were randomized (1:1) to either the BT group or the control group. During the 4-week baseline period, all subjects continued to receive maintenance therapy with inhaled corticosteroids and LABA for the first 2 weeks, and LABA were then withheld for the next 2 weeks. Therapy with inhaled corticosteroids and LABA was resumed for the treatment period, which lasted for at least 6 weeks and usually no more than 9 weeks. Subjects assigned to the BT group underwent three bronchoscopy procedures performed with the use of the Alair™ System at intervals of approximately 3 weeks. Control subjects had three office visits at intervals of 3 weeks for clinical review and assessment and received a systemic corticosteroid similar to that administered to subjects in the BT group. Seven subjects (three in the BT group

[2] For each subject, asthma was categorized as moderate and persistent or severe and persistent on the basis of the assessment of the subject's FEV1 value and the frequency of symptoms with the dose of maintenance therapy, according to the 2004 guidelines of the Global Initiative for Asthma for these measures (Cox et al., 2007).

and four in the control group) withdrew consent before the 3-month follow-up visit and 5 subjects (1 in the BT group and 4 in the control group) were lost to follow-up.

At 3 months subjects were asked to refrain from using LABA after this point (off-LABA), unless they had a severe exacerbation or if they were judged by the investigator to have poor asthma control that required the resumption of LABA. For those subjects whose asthma could be controlled without LABA, evaluations were performed after 6 and 12 months of treatment with ICS alone. Subjects who needed to resume LABA therapy were evaluated at those assessment points after withdrawal from LABA therapy for 2 weeks, during which data on exacerbations was collected.

The primary outcome measure in the AIR study was the change in the rate of mild exacerbations during the two-week abstinence period at 3 months, 6 months, and 12 months compared to baseline. Exacerbations, ascertained from daily diaries in which subjects recorded events, were defined as at least one of the following occurrences on 2 consecutive days:

- A reduction in the morning peak expiratory flow (PEF) of at least 20% below average (based on the PEF recorded during the week immediately preceding the withdrawal of LABA at baseline),
- The need for more than three additional puffs of rescue medication exceeding the average use during the week immediately preceding the withdrawal of LABA at baseline, or
- Nocturnal awakening caused by asthma symptoms.

Only events occurring during the 2-week periods of abstinence from LABA, according to the study protocol, at 3, 6, and 12 months, were used to calculate the rates of mild and severe exacerbations. The study design was based on the hypothesis that if BT were beneficial, then in subjects treated with BT, as compared with control subjects, asthma control would be improved when treatment with LABA was discontinued.

Secondary outcome measures include changes in pre- and post-bronchodilator FEV1, methacholine PC20 peak expiratory flow (morning and evening), use of rescue medication, use of maintenance medication, and scores on the AQLQ and ACQ at 3, 6, and 12 months.

All subjects kept a daily diary. The data recorded in the diaries were used to assess changes in the PEF, the use of rescue medication, the number of symptom-free days, and the symptom score.

At 12 months after the last study treatment, the mean number of mild exacerbations in the BT group was 0.18 ± 0.31 per subject per week, as compared with 0.35 ± 0.32 at baseline. The number of mild exacerbations in the control group was 0.31 ± 0.46 per subject per week, as compared with 0.28 ± 0.31 at baseline. The difference between the two groups in the change from baseline was significant at 3 months and at 12 months ($p = 0.03$ for both comparisons) but not at 6 months.

Overall, the average number of exacerbations during the two-week data collection periods at 3, 6 and 12 months when subjects were off-LABA was reduced in the BT group but did not significantly change in the control group (- 0.16 ± 0.37 vs 0.04 ± 0.2, per subject per week, $p = 0.005$ for the between group comparison.

In contrast, 12 months after the last study treatment, the mean number of severe exacerbations in the BT group was 0.01 ± 0.08 per subject per week, as compared with 0.07 ± 0.18 at baseline. The number of severe exacerbations in the control group was 0.0 6± 0.24 per subject per week, as compared with 0.09 ± 0.31 at baseline. The difference between the two groups in the change from baseline was not significant at any time point.

At 12 months, there were significantly greater improvements in the BT group than in the control group in the morning peak expiratory flow in the BT group, from 349.6 ± 90.6 at baseline to 388.6 ± 105.0 L/min, $p = 0.03$. This increase was also evident at 3 and 6 months. Change in FEV_1 was not different between groups at any time point. Airway responsiveness improved more in the BT group than the Control group. The differences over baseline between groups did not reach statistical significance at any time point. The BT group required significantly less short-acting bronchodilator than the Control group ($p = 0.04$). At 12 months, the BT group required 10.9 ± 15.0 puffs per week versus 19.8 ± 17.2 at baseline; the Control group required 14.8 ± 21.2 puffs per week at 12 months versus 16.0 ± 18.8 at baseline. The change in total symptom score was significantly reduced from baseline in the BT group (3.16 ± 2.21 to 1.25 ± 1.97) compared to the Control group (2.65 ± 2.55 to 2.00 ± 2.23) ($p = 0.01$). At 12 months, AQLQ score in the BT group changed from baseline from 4.91 ± 1.23 to 6.18 ± 0.88 and in the Control group from 5.15 ± 1.19 to 5.72 ± 1.11 ($p = 0.003$). Similarly, there was significant improvement over baseline in the ACQ score in the BT group (from 2.50 ± 0.92 to 1.32 ± 0.85) at 12 months compared to the Control group (from 2.16 ± 0.86 to 1.69 ± 0.99) ($p = 0.001$). Results for secondary outcomes are shown in Figure 3 in Cox et al., 2007 and described in detail in the Supplementary Materials.

There was an increase in adverse respiratory events in subjects undergoing BT immediately after the procedure, with a return to baseline values during the post-treatment period. Hospitalizations for adverse respiratory events during the treatment period were more frequent in the BT (four subjects required a total of six hospitalizations) than in the control group (two subjects required one hospitalization each). Four of the hospitalizations of subjects in the BT group were for exacerbation of asthma (one within 1 day after treatment, two 30 days after treatment, and one 85 days after treatment), one was for partial collapse of the left lower lobe (2 days after treatment), and one was for pleurisy (43 days after treatment). During the post-treatment period, the proportion of subjects with adverse respiratory events was similar in the two groups. The rate of hospitalization for respiratory events was low during this period and did not differ significantly between the two groups: three subjects in the bronchial-thermoplasty group required hospitalization — one for chest infection and two for asthma exacerbation — and two subjects in the control group required a total of three hospitalizations for increased asthma symptoms. There were no deaths during the study.

Asthma Intervention Research 2 (AIR2)
The purpose of this study was to evaluate the the safety and effectiveness of the BT versus a sham procedure in subjects with severe asthma who remain symptomatic despite treatment with high-dose inhaled corticosteroids and long-acting β2-agonists. Results of the AIR2 study were published by Castro et al., 2010. Eligibility for AIR2 (Clinicaltrials.gov NCT00231114) included:

- Adults between the ages of 18 and 65 years
- Asthma requiring daily maintenance medications of ICS (> 1,000 µg/d beclomethasone or equivalent) and a LABA (≥100 µg /d salmeterol or equivalent).
- Pre-bronchodilator Forced Expiratory Volume in one second (FEV1) of ≥ 60% of predicted
- Airway hyperresponsiveness (methacholine PC20 < 8 mg/ml per)
- At least two days of asthma symptoms during the 4-weeks of the Baseline Diary Period
- Non-smoker for 1 year or greater (if former smoker, less than 10 pack years total smoking history).

All randomized subjects were scheduled to undergo three bronchoscopy procedures performed 3 weeks apart. The treatment was administered by an unblinded bronchoscopy team. All follow-up and assessment visits were conducted by a blinded assessment team. Thus, neither the subject nor the assessor was aware of the individual treatment assignment. BT was performed by delivering radiofrequency energy to the airway using the Alair™ Bronchial Thermoplasty System. Subjects were evaluated 6 weeks after the last procedure (at the end of the treatment period). The posttreatment period extended from 6 to 52 weeks after the last procedure, and assessments were completed at 3, 6, 9, and 12 months. Subjects completed their daily diary from baseline to

12 weeks after the last procedure and over 4-week periods preceding the 6- and 12-month follow-up visits.

The primary outcome was the difference between study groups in the AQLQ score change from baseline to the average of the 6-, 9-, and 12-month scores (integrated AQLQ). The proportion of subjects within each group that achieved an AQLQ score change of 0.5 or greater (i.e., minimal important difference) was analyzed. Secondary outcomes included changes in: AQLQ (absolute and individual domains), ACQ scores, percentage of symptom-free days, symptom scores, morning PEF, rescue medication use, and FEV1. Additional outcomes included the numbers of severe asthma exacerbations (i.e., those requiring systemic corticosteroids or doubling of ICS dose), the percentage of subjects experiencing severe exacerbations, respiratory-related unscheduled physician office visits, emergency department (ED) visits, hospitalizations, and days missed from work/school or other activities due to asthma. The target posterior probability of superiority (PPS) of BT over sham was 95%, except for the primary AQLQ endpoint, where the target PPS was 96.4% (adjusted for two interim looks for early declaration of success).

Two-hundred and ninety-seven (297) subjects were randomized (2:1), 196 to the BT group and 101 to the sham control group. Two-hundred and eighty-eight (288) subjects underwent a bronchoscopy procedure, 190 in the BT group, and 98 in the sham control group. All 288 subjects qualified for the intent-to-treat and safety populations. Additionally, 268 subjects (173 in the BT group and 95 in the sham control group) qualified for inclusion in the per protocol population. The subjects enrolled in this trial had severe and inadequately controlled asthma as evidenced by the requirement for high-dose ICS and LABA, a high ACQ score consistent with poorly controlled asthma, and a low AQLQ score and percentage of symptom-free days. Analysis of the characteristics of these subjects demonstrated that 86% of the BT group (163 subjects) and 88% of the sham control group (86 subjects) met American Thoracic Society criteria for severe refractory asthma.

The mean change in integrated AQLQ score in the ITT population was greater in the BT group (1.35 ± 1.10) than in the sham group (1.16 ± 1.23; posterior probability of superiority (PPS), 96%), but this difference did not reach the planned PPS of 96.4%, therefore failing to meet the study's primary outcome. The mean change in integrated AQLQ score in the per protocol population was 1.38 ± 1.10 in the BT group and 1.14 ± 1.24 in the sham group (PPS, 97.9%). In the ITT population, a larger proportion of subjects in the BT group (79%) compared with the sham group (64%) had a clinically meaningful improvement in AQLQ score of 0.5 or greater (PPS, 99.6%). PPS, 99.6% means that there is a 99.6% likelihood that BT patients have a clinically meaningful improvement in AQLQ (i.e. improvement in AQLQ greater than 0.5) when compared to sham procedure. A smaller proportion of subjects in the BT group (3%) had a clinically meaningful deterioration in AQLQ of - 0.5 or less compared with the sham group (7%). The net benefit in AQLQ in this study was 76% (79–3%) in the BT group versus 57% (64–7%) in the sham group (PPS, 100.0%). Analysis of BT subjects suggested that responders, as defined by AQLQ score change of 0.5 or greater, had lower baseline AQLQ scores (responders: 4.1 ± 1.1 [n=150] vs. nonresponders: 5.1 ± 1.1 [n=40]; $p < 0.001$) and higher ACQ scores (responders: 2.2 ± 0.9 [n=150] vs. nonresponders: 1.9 ± 0.8 [n= 40]; $p < 0.041$).

The substantial mean improvement of 1.16 in AQLQ in the sham group suggests a large placebo effect, particularly for subjective outcomes such as quality of life.

During the posttreatment period, there was a 32% reduction in the rate of severe exacerbations in the BT group compared with the sham group (0.48 vs. 0.70 exacerbations/subject/yr, respectively; PPS, 95.5%). Of the BT subjects, 26.3% (50/190) experienced severe exacerbations, compared with 39.8% (39/98) of sham subjects (PPS, 99.0%). In the posttreatment period, subjects in the BT group reported fewer days lost from work/school or other activities due to asthma (1.32 ± 0.36 d/yr) compared with sham (3.92 ± 1.55 d/yr; PPS, 99.3%).

Secondary endpoint measures of morning PEF, symptom free days, symptom score, ACQ, and rescue medication use showed an improvement over baseline in the BT and sham groups, although the differences between the groups were not statistically significant (PPS, < 95.0%). Each of the four individual domains of AQLQ showed improvement in the BT group compared with sham, although statistical significance was reached only for the emotional function domain.

During the treatment period, both groups experienced an increase in respiratory adverse events, with more events reported in the BT (85% of subjects; 1.0 events/bronchoscopy) than in the sham group (76% of subjects; 0.7 events/bronchoscopy). The severity of respiratory adverse events for the BT and sham groups was as follows: mild, 43.6 versus 58.7%; moderate, 53.2 versus 39.8%; and severe, 3.1 versus 1.5%, respectively. The most common events were typical of airway irritation, including worsening asthma symptoms (wheezing, chest discomfort, cough, and chest pain), and upper respiratory tract infections. The majority of respiratory adverse events occurred within 1 day of the bronchoscopy and resolved within 7 days. During the treatment period, 16 subjects (8.4%) in the BT group required 19 hospitalizations for respiratory symptoms compared with two subjects (2.0%) in the sham group requiring two hospitalizations. Ten of the 19 hospitalizations in the BT group occurred on the day of the procedure.

During the post-treatment period, fewer adverse respiratory events were reported in the BT group (70% of subjects vs. 80% in the sham group). Consistent with this improvement in asthma, there was an 84% risk reduction in ED visits for respiratory symptoms in the BT group compared with sham group (0.07 vs. 0.43 visits/subject/yr; PPS 99.9%). Five subjects (2.6%) in the BT group had a total of six hospitalizations for respiratory symptoms (one subject had two hospitalizations), compared with 12 hospitalizations in four subjects (4.1%) in the sham group (one subject had nine hospitalizations).

Bronchoscopy in asthma is known to worsen symptoms and potentially induce complications, even more so in severe asthma. Data from this trial suggest that treatment with BT may further aggravate the airways in the short term. The adverse events after BT in this study were short in duration, as in previous trials, and patients responded well to therapy. Although there was an increase in respiratory adverse events in the BT group compared with the sham group in the treatment period, fewer subjects in the BT group reported respiratory adverse events in the posttreatment period.

AIR2 Extension Study to Demonstrate Longer-term (> 1 Year) Durability of Effectiveness (PAS1)

Results of the AIR2 Extension Study (Clinicaltrials.gov NCT01350414) were published by Wechsler et al., 2013. This was an open-label, single arm study designed to demonstrate the durability of effectiveness (beyond one year) of the Alair™ Bronchial Thermoplasty System in patients with severe persistent asthma. The study consists of subjects from the AIR2 trial (NCT00231114) who were in the BT group. Durability of treatment effect will be evaluated by comparison of the proportion of subjects experiencing severe exacerbations during the first year after the BT to subsequent 12-month periods out to 5 years. The 12-month periods will begin 6 weeks after the last BT treatment.

The secondary endpoints included the following additional safety endpoints for which data were being collected in the AIR2 trial:

- Severe exacerbation rates (exacerbations / subject / year)
- Respiratory adverse events (rates of respiratory adverse events, and proportion of subjects with respiratory adverse events)
- Emergency room visits for respiratory symptoms (rates of emergency room visits, and proportion of subjects with emergency room visits for respiratory symptoms)
- Hospitalizations for respiratory symptoms (rates of hospitalizations, and proportion of subjects with hospitalizations for respiratory symptoms)
- Respiratory Serious Adverse Events (detailed narratives will be provided for each event)

- Forced Expiratory Volume in 1 second (FEV_1)

Of the 190 subjects who underwent BT treatment in the AIR2 trial, 162 subjects (85.3%) completed the 5 year follow-up. The number of BT subjects completing annual follow-up at years 1, 2, 3, 4, and 5 was 181, 165, 162, 159, and 162, respectively. Twenty-eight (28) BT subjects (14.7%) did not complete the year 5 evaluation (18 were lost to follow-up, 4 were withdrawn by the investigators (terminal illness: 1; non-compliance with physician instructions: 3), 5 were withdrawn for nonmedical reasons, and 1 died in a motor vehicle accident). Four subjects missed the year 4 visit but remained in the study.

The proportion of subjects experiencing severe exacerbations and emergency room 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 prior to BT treatment (average 5 year reduction in proportions: 44% for exacerbations and 78% for ER visits). The reduction in proportion of subjects experiencing severe exacerbations in the year following BT (30.9%) compared to the 12 months before BT (51.6%) was maintained for the entire 5 year follow up period with an average decrease of 44% over this period. The decrease in severe exacerbation rates that was achieved in the posttreatment period following BT in year 1 was maintained out to 5 years. Compared to the 12 months prior to BT treatment, the average reduction over 5 years in the rate of severe exacerbations was 48%. The upper 95% confidence limit for the difference in percentages for years 2, 3, 4, and 5 compared to year 1 (subsequent year – year 1) was 0.5, 11.3, 14.0, and -1.6, respectively. All were less than the pre-defined non-inferiority margin of 20%. Exacerbations during years 2 to 5 were only ascertained at annual visits and confirmed by medical record review. This method of data collection differed from the use of diaries for recording exacerbations during the original study, and there was no information provided on the completeness or reliability of exacerbation reporting at the annual visits.

The decrease in the proportion of subjects experiencing ER visits for respiratory symptoms that was achieved following BT in year 1 was maintained out to 5 years. Compared to the 12 months before BT, the average reduction over the 5 years in proportion of subjects having ER visits for respiratory symptoms was 78%. The decrease in rates of ER visits that was achieved following BT in year 1 was maintained out to 5 years. Compared to the 12 months prior to BT treatment, the average reduction over 5 years in the rate of ER visits was 88%.

Bronchial Thermoplasty in Severe Persistent Asthma (PAS2)
PAS2 is a multicenter, open-label, single arm study designed to demonstrate durability of the treatment effect and to evaluate the short-term and longer-term safety profile of the Alair™ Bronchial Thermoplasty System in the United States in the intended use population (patients 18 years and older with severe persistent asthma). Three-year results of PAS2 were published by Chupp et al., 2017 and five-year results were published by Chupp et al., 2022.

Eligibility for PAS2 included:
- Adults between the ages of 18 and 65 years
- Asthma inadequately controlled despite optimized treatment with high ICS (> 1,000 µg/day beclomethasone or equivalent) and LABA (≥ 80 µg/day salmeterol or equivalent).
- Other asthma medications such as leukotriene modifiers, or anti-IgE therapy, are acceptable (subjects on Xolair® must have been on Xolair for greater than 1 year)
- OCS at a dosage of up to, but not greater than 10 mg per day are acceptable
- AQLQ score 6.25 or lower (a higher AQLQ score represents better quality of life)
- Prebronchodilator FEV1 >60% of predicted

Of 284 subjects enrolled, 279 (mean age 45.7 ± 11.6 years) were scheduled to undergo three bronchoscopy procedures performed 3 weeks apart. The right lower lobe of the lung was treated during the first session, the left lower lobe during the second session and both upper lobes during the third session.

PAS2 subjects were evaluated at each bronchoscopy visit and at 6 weeks after the last procedure (the end of the treatment period). Subsequently, subjects were scheduled to be seen at annual office visits up to 5 years after the bronchial thermoplasty treatments. Subjects were also contacted by phone every 3 months between annual office visits.

The primary end-point of the PAS2 study was the proportion of subjects experiencing severe exacerbations during the subsequent 12-month period (for years 2, 3, 4 and 5) compared with the first 12-month period after bronchial thermoplasty. A severe exacerbation is defined for the PAS2 study as a worsening of asthma symptoms requiring the use of systemic corticosteroids (tablets, suspension or injection). For subjects already taking OCSs on a daily or alternate-day basis, a severe exacerbation is defined as a worsening of symptoms requiring an increase in the daily dose of systemic corticosteroids. This definition is consistent with the National Asthma Education and Prevention Program Guidelines for the Diagnosis and Management of Asthma. Unlike the AIR2 trial, the PAS2 study did not include a doubling of ICS dose as part of the definition of a severe exacerbation. Other end-points related to the safety of the Alair system include respiratory adverse events, serious adverse events, and measurements for pre- and post-bronchodilator FEV_1.

The secondary endpoints included the following additional safety endpoints which will be evaluated annually through year 5:

- Severe exacerbation rates (exacerbations / subject / year)
- Respiratory adverse events (rates of respiratory adverse events, and proportion of subjects with respiratory adverse events)
- Emergency room visits for respiratory symptoms (rates of emergency room visits, and proportion of subjects with emergency room visits for respiratory symptoms)
- Hospitalizations for respiratory symptoms (rates of hospitalizations, and proportion of subjects with hospitalizations for respiratory symptoms)
- Respiratory Serious Adverse Events (detailed narratives will be provided for each event)
- Forced Expiratory Volume in 1 second (FEV_1)

Two-hundred and eighty-four (284) subjects were enrolled at 27 centers and 227 (80%) subjects completed 5 years of follow-up. By year 5 post-treatment, the proportion of subjects with severe exacerbations, emergency department visits, and hospitalizations was 42.7%, 7.9%, and 4.8%, respectively, compared to 77.8%, 29.4%, and 16.1% in the 12 months prior to treatment. Of note, a larger proportion of the 52 individuals who were not followed for five years experienced severe exacerbations (92.3% vs 74.4%), emergency department visits (51.9% vs. 24.2%), and hospitalizations (30.8% vs. 12.8%) during the 12 months before BT compared with the 227 subjects who were followed for 5 years, indicating those who dropped out of PAS2 may have had more serious disease and were not included in the analysis.

During the 12 months prior to BT, 77.8% of subjects experienced at least one severe exacerbation, compared to 50.4% after 1 year, 46.8% after 2 years, 47.0.% after 3 years, 44.2% after 4 years, and 42.7%, after 5 years of follow-up (77.8% vs. 50.4%, 46.8%, 47.0%, 44.2%, and 42.7%, $p<0.001$). There was also a significant reduction in the rate of severe exacerbations from baseline (1.61 exacerbations/subject) to 5 years (0.72 exacerbations/subject; $p<0.001$). There were 61.8% (68/110) subjects with ≤ 1 severe exacerbations during the 12 months prior to BT who experienced ≤ 1 severe exacerbation per year following BT treatment compared to 35.0% (41/117) subjects with ≥ 2 severe exacerbations during the 12 months prior to BT.

The proportion of subjects with ED visits significantly decreased from 29.4% during the 12 months prior to BT to 18.3%, 14.7%, 13.0%, 11.7%, and 7.9% during Years 1 through 5, respectively, after BT ($p< 0.001$). ED visit rates were also reduced from 0.54 ED visits/subject in the 12 months prior to BT to 0.13 ED visits/subject in Year 5 ($p=0.0002$).

A decrease in hospitalizations was also observed after BT; 16.1% of subjects were hospitalized for asthma in the year prior to BT, but during Years 1-5, only 8.0%, 7.5%, 7.3%, 3.3%, and 4.8%, respectively, were hospitalized (p=0.0003). Annual hospitalization rates fell from 0.22 hospitalizations/subject at baseline to 0.06 hospitalizations/subject at Year 5 after BT (p=0.0012). Spirometry was performed at baseline and at yearly follow-up visits for all subjects. BT did not alter spirometry parameters as reported in previous studies.

PAS2 subjects reduced asthma maintenance medications. Notably, clinical improvements were accompanied by a reduction in corticosteroid exposure. The mean daily dose of inhaled corticosteroids was decreased from 2272 µg/day (beclomethasone or equivalent) at baseline to 1928 µg/day, by Year 5 post-BT.

The percentage of subjects using biologic medications for asthma control remained relatively constant (15.8%-18.5%) over the course of the study. At baseline, omalizumab was used exclusively. In subsequent years, some subjects began using mepolizumab, benralizumab, and reslizumab as these monoclonal antibodies were introduced. Additionally, 54 (54/279: 19.4%) subjects were taking maintenance OCS at the baseline visit. After BT treatment, 10.7%, 10.2%, 10.0%, 8.1%, and 9.7% of subjects were taking maintenance OCS at the 1-5-year follow-up visits, respectively. Twenty-two (42%) of the 54 subjects taking OCS at baseline discontinued OCS after BT. The proportion of subjects with severe exacerbations among those 22 fell from 95.5% at baseline to 50.0% at Year 5 following BT treatment. Clinical improvements in the 32 subjects who continued taking OCS medications after BT were similar. In this case, 18/32 subjects also used a biologic for asthma maintenance. The proportion of the 32 subjects experiencing severe exacerbations was reduced from 93.8% at baseline to 51.9% at Year 5 after BT. Only 9 subjects who were not taking OCS at baseline began taking these medications for asthma control after BT. These patients did not experience a reduction in severe exacerbations.
Bronchoscopic procedures can worsen asthma-related symptoms in the short term and induce other complications in severe asthmatics. While the percentage of subjects with periprocedural respiratory serious AEs (requiring hospitalization or prolongation of hospitalization) during the treatment phase was 14.7%, respiratory serious AEs were reduced during the post-treatment phase to 9.4% during Year 1 after BT and to 4.7% during Year 5 after BT.

During this study, 4 deaths, all unrelated to BT, occurred. Two males, aged 50 and 55 years, died of cardiac arrest. The 55-year-old male was found unresponsive (pulseless and asystolic) at home approximately 3 years after the third BT procedure. The 50-year-old male died of cardiac arrest shortly after completing the third BT treatment. A 57-year-old female subject died of myocardial infarction approximately two years after the final BT treatment after cardiac catheterization/stenting for severe arterial stenoses failed. A 53-year-old male died approximately 3 years after his last BT procedure of unknown causes. This subject had severe obstructive sleep apnea and died in his sleep; no autopsy was performed.

Practice Guidelines

National Asthma Education and Prevention Program

In 2020, the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group published Focused Updates to the Asthma Management Guidelines. This update was based on evidence published by the Agency for Healthcare Research and Quality (AHRQ) (D'Anci KE et al., 2017).

Section VII. Recommendations for the Use of Bronchial Thermoplasty to Improve Asthma Outcomes

Question 7.1 What are the benefits and harms of using BT in addition to standard treatment for the treatment of individuals ages 18 years and older with asthma?

In individuals ages 18 years and older with persistent asthma, the Expert Panel conditionally recommends against bronchial thermoplasty. (Conditional Recommendation, low certainty of evidence)

Individuals ages 18 years and older with persistent asthma who place a low value on harms (i.e., short-term worsening of symptoms and unknown long-term side effects) and a high value on potential benefits (i.e., improvement in quality of life and a small reduction in number of exacerbations) might consider BT.

Clinician's Summary:
Most individuals ages 18 years and older with uncontrolled, moderate-to-severe, persistent asthma should not undergo BT to treat asthma because the benefits are small, the risks are moderate, and the long-term outcomes are uncertain. Some individuals with moderate-to-severe persistent asthma who have troublesome symptoms may be willing to accept the risks of BT and, therefore, might choose this intervention after shared decision-making with their health care provider. Clinicians should offer the procedure in the setting of a clinical trial or a registry study to enable the collection of long-term data on the use of BT for asthma.

Analysis of Evidence (Rationale for Determination)

Two RCTs compared bronchial thermoplasty (BT) with standard care (Pavord et al., 2007, Cox et al., 20007). The Research In Severe Asthma (RISA) study (N = 32) enrolled individuals treated with a high-dose inhaled corticosteroids (ICS) (more than 750 mcg fluticasone or equivalent) and a long-acting beta2-agonist (LABA) (100 mcg salmeterol equivalent) with or without daily oral corticosteroids (less than 30 mg/day prednisone equivalent). The Asthma Intervention Research (AIR) study (N = 112) enrolled individuals taking an ICS (more than 200 mcg/day beclomethasone equivalent) and a LABA (100 mcg salmeterol or equivalent). A third study, Asthma Intervention Research 2 (AIR2) (N = 288), compared BT with sham bronchoscopy. This study enrolled individuals treated with high-dose ICS (more than 1,000 mcg betamethasone or equivalent) plus a LABA. Participants could also continue using other asthma medications such as leukotriene modifiers, anti-IgE therapy (subjects on Xolair® must have been on Xolair® for > 1 year), or OCS at a dose ≤ 10 mg/day.

BT and standard care improved asthma control, defined by the Asthma Control Questionnaire (ACQ) change from baseline to 12 months and Asthma Quality of Life Questionnaire (AQLQ) scores, more than standard care alone to a degree that was statistically significant. However the minimally important difference was not met for these measures and therefore the clinical importance of these improvements is uncertain. BT and standard care, compared with sham bronchoscopy and standard care did not improve asthma control (defined as ACQ change from baseline to 12 months, or AQLQ scores in the intent-to-treat (ITT) analysis.

In the FDA Summary of Safety and Effectiveness for The Alair™ Thermal Bronchoscopy System (PMA P080032), XIII. A. Safety Conclusions, the FDA notes that while there were some differences between groups in certain adverse events, there were no general trends to indicate a safety risk in the pivotal trial (AIR2). In XIII. B. Effectiveness Conclusions, the FDA notes that the primary effectiveness endpoint in the pivotal trial (AIR2) examined the difference between AQLQ scores between the treatment and sham arms, and that this analysis did not meet its prespecified success criterion. The results of the primary effectiveness endpoint is not the basis of approval. The FDA notes that the most important clinical performance measure in the pivotal trial (AIR2) is severe asthma exacerbations. Results from AIR2 showed a clinically significant difference in severe asthma exacerbations in favor of the BT group. During the post-treatment phase, the severe exacerbation rate was 0.48 exacerbations/subject/year in the BT group and 0.70 exacerbations/subject/year in the Sham group (PPS, 95.5%). Other endpoints that could be expected to correlate with severe asthma exacerbations, including emergency room visits for respiratory symptoms; hospitalizations for respiratory symptoms, rescue medication use; asthma symptoms, days lost from work, school or other activities, unscheduled office visits for respiratory

symptoms – all showed differences in favor of the BT group. The majority of these other endpoints did not reach clinical significance but did favor BT over the sham group, and while results that do not exhibit clinical significance cannot be a basis of approval, they add to the totality of the effectiveness data.

The FDA directed the manufacturer to conduct two post-approval studies to evaluate durability of effectiveness of the Alair™ System in patients with severe, persistent asthma for 5 years. The primary endpoint in both post-approval studies was the proportion of subjects experiencing severe exacerbations during the first year after BT compared to subsequent 12-month periods out to 5 years. In AIR2 Extension (PAS1), the proportion of subjects experiencing severe exacerbations and emergency room 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 prior to BT treatment (average 5 year reduction in proportions: 44% for exacerbations and 78% for ER visits). In PAS2, during the 12 months prior to BT, 77.8% of subjects experienced at least one severe exacerbation, compared to 50.4% after 1 year, 46.8% after 2 years, 47.0.% after 3 years, 44.2% after 4 years, and 42.7%, after 5 years of follow-up (77.8% vs. 50.4%, 46.8%, 47.0%, 44.2%, and 42.7%, $p<0.001$). There was also a significant reduction in the rate of severe exacerbations from baseline (1.61 exacerbations/subject) to 5 years (0.72 exacerbations/subject; $p<0.001$). Similarly, the proportion of subjects with ER visits significantly decreased from 29.4% during the 12 months prior to BT to 18.3%, 14.7%, 13.0%, 11.7%, and 7.9% during years 1 through 5, respectively, after BT ($p< 0.001$). Er visit rates were also reduced from 0.54 Er visits/subject in the 12 months prior to BT to 0.13 Er visits/subject in Year 5 ($p=0.0002$).

The data on the benefits and harms of BT derive primarily from three RCTs that enrolled a total of 432 patients. In these RCTs, medical therapy consisted of medium to high doses of inhaled corticosteroid (ICS) treatment, long acting β2 agonists (LABAs), omalizumab (in one study), and/or oral corticosteroids. Available studies of BT did not include individuals treated with long-acting muscarinic antagonists, environmental interventions, and/or newer biologic agents. Clinicians should optimize asthma treatment and address comorbidities, and they should assess and optimize adherence to existing therapy, before considering BT. BT has not been studied in individuals younger than age 18 years. BT may offer an acceptable benefit-to-harm ratio for some patients after careful shared decision-making. Further research that includes randomized trials as well as long-term registry outcomes are desirable.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

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
C1886	Catheter, extravascular tissue ablation, any modality (insertable)

HCPCS Level II C Codes

HCPCS Level II C-Codes only apply to hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) claims reimbursed under Medicare payment methodology.

Per CMS guidance, hospitals reimbursed under Medicare OPPS payment methodology should report device category HCPCS codes on claims whenever they are provided in the hospital outpatient setting (Medicare Claims Processing Manual, Chapter 4, Section 10.4), regardless of whether payment for the services is made separately or packaged. Conversely, ASCs should not report packaged codes since they are not reportable under the ASC payment system.

HCPCS Level II C-Codes are not payable under MassHealth.

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Policy history

Origination date:	06/01/2018
Review/Approval(s):	Technology Assessment Committee: 05/15/2018 (Introduced as a new policy), 05/22/2019 (updated references), 10/27/2020 (updated criteria to include additional contraindications, updated references); 6/22/2021 (annual review, no changes), 06/15/2021 (Added clarifying language related to Medicare Advantage, MassHealth, NaviCare and PACE under Policy section), 02/27/2024 (annual review, added new sections: Summary of Evidence and Analysis of Evidence (Rationale for Determination), updated references), 02/25/2025 (annual review, updated coverage criteria, adding: if former smoker, less than 10 pack years total smoking history, updated Summary of Evidence and References). Utilization Management Committee: 03/18/2025 (review and approval).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.