Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

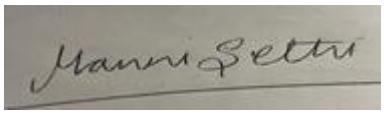
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 4/1/2025
Policy Number: ccp.1058	Effective Date: 10/2023 Revision Date: 3/2025
Policy Name: Bronchial thermoplasty for severe asthma	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Bronchial thermoplasty for severe asthma

Clinical Policy ID: CCP.1058

Recent review date: 3/2025

Next review date: 7/2026

Policy contains: Asthma, bronchial thermoplasty, inhaled corticosteroids, long acting beta agonists.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Bronchial thermoplasty is clinically proven and, therefore, may be medically necessary for severe asthma when all of the following criteria are met (Global Initiative for Asthma, 2024; Tan, 2019):

- The member has a confirmed diagnosis of severe asthma.
- Severe asthma persists despite adherence to appropriate pharmacologic and non-pharmacologic interventions, including high-dose inhaled corticosteroids and long-acting beta agonists, and having failed treatment with, or has contraindications to, biologics.

<u>Member does not have a comorbidity that could affect asthma control, including either:</u>

- Gastroesophageal reflux disease, postnasal drip, or obstructive sleep that is not well-controlled or adequately treated.
- Smoking.
- Vocal cord dysfunction.
- Chronic sinus disease or frequent chest infections.
- Other comorbidities that are not well-controlled.
- Medication adherence continues and proper inhaler technique are used and reinforced.
- Member is able to undergo bronchoscopy safely.

Contraindications to bronchial thermoplasty are ruled out, including:

- Implantable electronic device.
- Member is under 18 years of age.
- Member was previously treated with bronchial thermoplasty.
- Members with a forced expiratory volume in one second < 60% of predicted should be selected with caution.

Limitations

- No limitations were identified during the writing of this policy.

Alternative covered services

- Beta agonists.
- Inhaled corticosteroids.

Background

Asthma is a common chronic airway disorder characterized by periods of reversible airflow obstruction (Asthma and Allergy Foundation of America, 2022). Airflow is obstructed by inflammation and bronchial muscle hyper-reactivity in response to certain exposures, such as exercise, infection, allergens (e.g., pollen), occupational agents (e.g., chemicals), and airborne irritants (e.g., environmental tobacco smoke). Symptoms may include wheezing, coughing, shortness of breath, and chest tightness. It is not clear how to prevent asthma from developing, and there is no cure.

Currently, approximately 25 million Americans have asthma, including 5.1 million children under age 18. Asthma rates have been rising for all ages, racial groups, and genders since the 1980s. In 2018, asthma accounted for 58 million doctor's office visits, 178,530 hospital discharges, and 1.6 million emergency department visits (Asthma and Allergy Foundation of America, 2022).

The means to controlling and preventing exacerbations in persons who have asthma are well established in evidence-based clinical guidelines (Hashmi, 2022). Current guidelines emphasize that asthma therapy be selected on the basis of disease severity. Rapid-acting and long-acting inhaled β2-agonists, controller medications using daily inhaled glucocorticoids, and sustained-release theophylline, chromones, or leukotriene modifiers may be prescribed. Some patients with severe asthma do not achieve acceptable control despite maximal medical therapy (Hashmi, 2022).

Bronchial thermoplasty is an endoscopic procedure that applies radiofrequency energy through an expandable array of electrodes to ablate bronchial smooth muscle that constricts the airways during asthma attacks (Hashmi, 2022). It is intended for the treatment of severe, persistent asthma not well controlled by long-acting bronchodilators or glucocorticoids, in patients 18 years and older.

The U.S. Food and Drug Administration (2010) approved one device, the Alair™ Bronchial Thermoplasty System (Boston Scientific Corporation, Marlborough, Massachusetts) based on acceptable safety and efficacy data reported from the Asthma Intervention Research 2 (AIR2) Trial (ClinicalTrials.gov identifier: NCT00231114; Castro, 2010, 2011; Wechsler, 2013). The complete thermoplasty procedure is performed in three treatment sessions targeting different segments of the lung, with a recovery period of at least three weeks between each session (Boston Scientific Corporation, 2023). It is typically performed by a pulmonologist, with the patient under moderate sedation or general anesthesia.

Findings

A number of guidelines from professional societies support the use of bronchial thermoplasty as an add-on treatment for selected patients with severe asthma (American College of Chest Physicians, 2014; Global Initiative for Asthma, 2020, updated 2021; Healthcare Improvement Scotland, 2019). However, some of these sources caution that the evidence supporting use of this treatment is limited, and that clinicians should carefully advise patients of potential risks and benefits before therapy begins.

The European Respiratory Society/American Thoracic Society Task Force on severe asthma recommends bronchial thermoplasty be performed in adults with severe asthma only for an Institutional Review Board registry or a clinical study, due to the low confidence in data in published studies (Chung, 2014).

A guideline stated that current evidence supports the use of bronchial thermoplasty for severe asthma, providing it is performed by a multidisciplinary team in specialist centers. The guideline acknowledges that more research on safety and efficacy is needed (National Institute for Health and Care Excellence, 2018).

The National Asthma Education and Prevention Program Coordinating Committee Working Group of the National Heart, Lung, and Blood Institute's December 2020 update to its asthma management guideline included bronchial thermoplasty as one of its six topics. The panel did not recommend bronchial thermoplasty as part of standard asthma care, unless included as part of an ongoing research effort (Cloutier, 2020).

A review by the Agency for Healthcare Quality and Research evaluated 15 studies (n = 432), three of which were randomized controlled trials, for persons with severe asthma. Outcomes after bronchial thermoplasty plus standard care (continued medical management) versus sham bronchial thermoplasty plus standard care were compared. Asthma control, hospitalizations for respiratory symptoms, use of rescue medications, pulmonary physiology measures, or quality of life scores were not significantly different between groups. Bronchial thermoplasty was linked with fewer severe exacerbations and emergency visits, but also with higher rates of hospitalization (D'Anci, 2017).

A Cochrane review of three randomized controlled trials of 249 patients with severe persistent asthma compared bronchial thermoplasty with medical management or a sham intervention (Torrego, 2014). Results showed that bronchial thermoplasty, in comparison with other groups:

- Improved quality of life at 12 months, a finding not clinically significant.
- Had the same level of symptom control.
- Showed a lower rate of exacerbation and emergency department visits (8.4% versus 15.3%) after 12 months.
- Documented no significant improvement in pulmonary function parameters (with the exception of a greater increase in morning peak expiratory flow in one trial).
- Had a significantly greater hospitalization risk for respiratory adverse events during treatment (risk ratio 3.50), representing an increase from 2% to 8% over the treatment period.
- Was associated with a rise in respiratory adverse events, mainly during the treatment period.

Of the bronchial thermoplasty subjects in the meta-analysis, 216 were followed for five years after treatment. The frequency of respiratory adverse events were significantly reduced ($P < .00001$). The number of emergency visits and hospitalizations for adverse events were (non-significantly) different over time, at $P = .71$ and $P = .32$ (Zhou, 2016).

A systematic review of three trials evaluated the efficacy of bronchial thermoplasty with omalizumab (Xolair), a monoclonal antibody to treat asthma, both compared with sham treatments or placebo. Bronchial thermoplasty

patients experienced (insignificantly) fewer severe exacerbations (*P* = .62) and hospitalizations (*P* = .53) but significantly fewer emergency department visits (*P* = .04). Scores on the asthma quality-of-life questionnaire were higher for the bronchial thermoplasty group (borderline significant at *P* = .059). The rate of exacerbations for bronchial thermoplasty was significantly higher at *P* < .009 (Niven, 2018).

The AIR2 trial first compared 190 subjects in the bronchial thermoplasty group and 98 in the sham group one year after treatment. Bronchial thermoplasty consistently showed superior efficacy in net benefit in Asthma Quality of Life Questionnaire score (76% versus 57%), percent with severe exacerbations (26.3% versus 39.8%), average days per year lost from work and school (1.32 versus 3.92), percent of subjects with adverse respiratory events reported (70% versus 80%), and emergency visits per subject per year for respiratory symptoms (0.07 versus 0.43) (Castro, 2010). Similar results were observed after the second year post-treatment (Castro, 2011). After three years, the percent of the 190 subjects with severe exacerbations, emergency department visits and hospitalizations significantly decreased by 45%, 55%, and 40%, respectively (Chupp, 2017).

A report updating AIR2 results of 162 subjects in the bronchial thermoplasty group compared results in the year prior to treatment with the five years after treatment. A 48% reduction in exacerbation and 88% reduction in emergency visits in the bronchial thermoplasty group were both significant. No changes were observed in pre-bronchial thermoplasty Forced Expiratory Volume or respiratory-related adverse events, and hospitalizations (Wechsler, 2013).

A longitudinal cohort study of 131 subjects given bronchial thermoplasty for severe asthma reviewed safety and efficacy data at baseline versus 12 months later. Quality of life scores improved significantly (*P* = .0003). Reduction in hospital admission rate after 24 months was also significant (*P* < .0001). No deterioration in forced expiratory volume was observed. In addition, 18.9% of 370 procedures and 44.5% of 128 patients had an adverse event; only a few were considered serious (Burn, 2019).

In 2022, we updated the references and added two new studies. The “Bronchial Thermoplasty 10+ Year Study” (BT10+) enrolled 192 (45%) of the 429 participants originally enrolled in the Asthma Intervention Research, AIR2, and Research in Severe Asthma randomized controlled trials (Chaudhuri, 2021; ClinicalTrials.gov identifier NCT03243292). Baseline characteristics were similar between participants enrolled in BT10+ and those not enrolled. The efficacy of bronchial thermoplasty observed at five year follow up was sustained for 10 years or longer, in terms of rates of severe exacerbations and hospital emergency department visits, with an acceptable safety profile.

The “Unravelling Targets of Therapy in Bronchial Thermoplasty in Severe Asthma” (TASMA) trial randomized 40 patients with severe asthma to immediate or delayed bronchial thermoplasty treatment to assess the treatment effects on airway smooth muscle mass and to identify patient correlates of treatment response (Goorsenberg, 2021; ClinicalTrials.gov identifier NCT02225392). Patients were assessed six months after treatment. Median airway smooth muscle mass significantly decreased by > 50% in the immediate treatment group (n = 17) versus no change in the delayed control group (n = 19) (*P* = .0004). As measures of treatment response, Asthma Control Questionnaire scores and Asthma Quality of Life questionnaire scores significantly improved in the immediate treatment group compared with the delayed treatment group (*P* = .006 and *P* = .04, respectively). There was no correlation between airway smooth muscle mass and changes in treatment response, but there were significant correlations between blood eosinophil counts and total Immunoglobulin E at baseline and bronchial thermoplasty response. No policy changes are warranted.

In 2023, five-year outcomes from the open-label , observational, multicenter Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma (PAS2) study showed statistically significant improvement in severe exacerbations, hospitalizations, emergency department visits, and corticosteroid exposure from baseline in adult patients with severe asthma who underwent bronchial thermoplasty (Chupp,

2022; ClinicalTrials.gov identifier NCT01350336, n = 284, 227 completed the study). No policy changes are warranted.

In 2024, we found a meta-analysis of 29 randomized controlled (n = 15,547), bronchial thermoplasty was evaluated for severe asthma compared to controls and biological therapies. Fewer patients treated with bronchial thermoplasty experienced at least one asthma exacerbation compared to the control group, with a reported risk ratio of 0.66 and a 95% confidence interval of 0.45–0.98. Significant improvements were observed in bronchial thermoplasty patients in terms of Asthma Control Questionnaire score and Asthma Quality of Life Questionnaire score with mean differences of −0.41 (95% confidence interval -0.63 to −0.20) and 0.54 (95% confidence interval = 0.30–0.77) respectively. Despite the lack of direct comparative trials, the network meta-analysis suggests bronchial thermoplasty is a viable alternative for patients with severe asthma, with comparable outcomes to biological therapies (Fong, 2023). No policy changes are warranted.

In 2025, revised the policy based on updated guidelines from the Global Initiative for Asthma (2024).

References

On Febuary 15, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “asthma,” “bronchial thermoplasty (MeSH),” and “bronchial thermoplasty.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

3/2013: initial review date and clinical policy effective date: 10/2013

3/2020: Coverage changed from investigational to medically necessary (see coverage section for explanations, and additional references).

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.

3/2025: Policy references updated.