PHP_7.01.127	Bronchial Thermoplasty		
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Section:	7.0 Surgery	**Page:**	Page 1 of 20

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

I. Bronchial thermoplasty for the treatment of asthma is considered **investigational**.

Policy Guidelines

Coding

See the Codes table for details.

Description

Bronchial thermoplasty is a potential treatment option for individuals with severe persistent asthma. It consists of radiofrequency energy delivered to the distal airways with the aim of decreasing smooth muscle mass believed to be associated with airway inflammation.

Summary of Evidence

For individuals who have asthma refractory to standard treatment who receive bronchial thermoplasty added to medical management, the evidence includes 3 randomized controlled trials (RCTs) and observational studies. Relevant outcomes are symptoms, quality of life (QOL), hospitalizations, and treatment-related morbidity. Early studies (Research in Severe Asthma [RISA], Asthma Intervention Research [AIR]) investigated safety outcomes, finding similar rates of adverse events and exacerbations between the bronchial thermoplasty and control groups. These trials were limited by their lack of sham control. The AIR2 trial is the largest of the 3 published RCTs, and the only trial that is double-blind and sham-controlled, with sites in the United States. Over 1 year, bronchial thermoplasty was not found to be superior to sham treatment on the investigator-designated primary efficacy outcome of mean change in the QOL score but was found to be superior on a related outcome, improvement in the QOL of at least 0.5 points on the Asthma Quality of Life Questionnaire (AQLQ). There was a high response rate in the sham group of the AIR2 trial, suggesting a large placebo effect, particularly for subjective outcomes such as QOL. There are limited long-term sham-controlled efficacy data. Findings on adverse events from the 3 trials have suggested that bronchial thermoplasty is associated with a relatively high rate of adverse events, including hospitalizations during the treatment period, but not in the posttreatment period. Safety data up to 10 years have been reported for patients in the AIR2 trial, with a higher rate of new cases of bronchiectasis observed in bronchial thermoplasty-treated patients. Data from a United Kingdom registry showed that 20% of bronchial thermoplasty procedures were associated with a safety event (i.e., procedural complications, emergency respiratory readmissions, emergency department visits, and/or postprocedure overnight stays) with uncertain benefit. Conclusions cannot be drawn about

the effect of bronchial thermoplasty on the net health outcome due to the limited amount of sham-controlled data (1 RCT) on short-term efficacy, the uncertain degree of treatment benefit in that single sham-controlled trial, the lack of sufficient long-term sham-controlled data in the face of a high initial placebo response, and the presence of substantial adverse events. Also, there is a lack of data on patient selection factors for this procedure and, as a result, it is not possible to determine whether there are patient subgroups that might benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

Regulatory Status

In April 2010, the Alair® Bronchial Thermoplasty System (Asthmatx, now Boston Scientific) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P080032) for use in adults with severe and persistent asthma whose symptoms are not adequately controlled with low-dose ICS and LABA. Use of the treatment is contraindicated in patients with implantable devices and those with sensitivities to lidocaine, atropine, or benzodiazepines. It should also not be used while patients are experiencing an asthma exacerbation, active respiratory infection, bleeding disorder, or within 2 weeks of making changes in their corticosteroid regimen. The same area of the lung should not be treated more than once with bronchial thermoplasty. FDA product code: OOY.

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

Background

Asthma

Asthma, a chronic lung disease, affects approximately 8.4% of adults and 5.8% of children in the United States (U.S.).[1] As of 2018, 14.3% of Black children under 18 in the U.S. had asthma, followed by 8% of Hispanic children, 5.6% of White children, and 3.6% of Asian children.[2] In the U.S., the burden of asthma falls disproportionately on Black, Hispanic, and American Indian/Alaska Native individuals; these groups have the highest rates, deaths, and hospitalizations.[3] Compared to White Americans, Black Americans are 1.5 times more likely to have asthma, and Puerto Rican Americans are almost 2 times more likely to have asthma. In 2018 and 2020, asthma exacerbations accounted for approximately 1.6 million emergency department visits and 4145 deaths overall, respectively.[1] Black Americans are 5 times more likely than White Americans to visit the emergency department for asthma and 3 times more likely to die from asthma.[3] Asthma symptoms include episodic shortness of breath that is generally associated with other symptoms such as wheezing, coughing, and chest tightness. Objective clinical features include bronchial hyperresponsiveness, airway inflammation, and reversible airflow obstruction (at least 12% improvement in forced expiratory volume in 1-second post-bronchodilator, with a minimum of 200 mL improvement). However, there is substantial heterogeneity in the inflammatory features of patients diagnosed with asthma, and this biologic diversity is responsible, at least in part, for the variable response to treatment in the asthma population.

Management

Management of asthma consists of environmental control, patient education, management of comorbidities, and regular follow-up for affected patients, as well as a stepped approach to medication treatment. Guidelines from the National Heart, Lung and Blood Institute have defined 6 pharmacologic steps: step 1 for intermittent asthma and steps 2 through 6 for persistent asthma.[4] The preferred daily medications: step 1: short-acting ß-agonists as-needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting ß-agonists (LABA) or medium-dose ICS; step 4: medium-dose ICS and LABA; step 5: high-dose ICS and LABA; and step 6: high-dose ICS and LABA, and oral corticosteroids. A focused update in 2020 addressed the use of add-on long-acting antimuscarinic agents (LAMA), immunotherapy, and bronchial thermoplasty (see Practice Guidelines and Position Statements).

Despite this multidimensional approach, many patients continue to experience considerable morbidity. In addition to ongoing efforts to implement optimally standard approaches to asthma treatment, new therapies are being developed. One recently developed therapy is bronchial thermoplasty, the controlled delivery of radiofrequency energy to heat tissues in the distal airways. Bronchial thermoplasty is based on the premise that patients with asthma have an increased amount of smooth muscle in the airway and that contraction of this smooth muscle is a major cause of airway constriction. The thermal energy delivered via bronchial thermoplasty aims to reduce the amount of smooth muscle and thereby decrease muscle-mediated bronchoconstriction with the ultimate goal of reducing asthma-related morbidity. A typical full course of treatment consists of 3, one hour sessions, given 3 weeks apart under moderate sedation. All accessible airways distal to the main stem bronchus that are 3 to 10 mm in diameter are treated once, except those in the right middle lobe. The lower lobes are treated first followed by the upper lung. Bronchial thermoplasty is intended for consideration as a supplemental treatment for patients with severe persistent asthma (i.e., steps 5 and 6 in the stepwise approach to care).

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL),

and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Bronchial Thermoplasty for the Treatment of Asthma

Clinical Context and Therapy Purpose

The purpose of bronchial thermoplasty in individuals who have asthma refractory to standard treatment is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with persistent and severe asthma whose symptoms are not adequately controlled with low-dose inhaled corticosteroids (ICS) and long-acting ß-agonists (LABAs). Asthma symptoms can vary between individuals but may include bronchial hyperresponsiveness, airway inflammation, and reversible airflow obstruction.

Interventions

The therapy being considered is bronchial thermoplasty as an add-on treatment in patients whose asthma is not adequately controlled with medical management.

Bronchial thermoplasty procedures are performed on an outpatient basis, and each session lasts approximately 1 hour. During the procedure, a standard flexible bronchoscope is placed through the patient's mouth or nose into the most distal targeted airway, and a catheter is inserted into the working channel of the bronchoscope. After placement, the electrode array in the top of the catheter is expanded, and radiofrequency energy is delivered from a proprietary controller and used to heat tissue to 65°C over a 5-mm area. The positioning of the catheter and application of thermal energy is repeated several times in contiguous areas along the accessible length of the airway. At the end of the treatment session, the catheter and bronchoscope are removed. A course of treatment consists of 3 separate procedures in different regions of the lung scheduled about 3 weeks apart.

Comparators

Currently, clinical response to continued medical management is being used to make decisions about the use of bronchial thermoplasty for treatment-refractory asthma. Continued medical management of asthma consists of environmental control, patient education, management of comorbidities, and regular follow-up for affected patients, as well as a stepped approach to medication treatment with bronchodilators, corticosteroids, and biologics.

Outcomes

Beneficial outcomes are symptom relief, improvement in QOL, reductions in medication adverse events and hospitalizations, reduced use of rescue medications, and treatment-related morbidity. Instruments such as the Asthma Quality of Life Questionnaire (AQLQ) score and the Asthma Control Questionnaire (ACQ) may be used to assess improvements in asthma symptoms. A minimal clinically important difference (MCID) in the AQLQ and ACQ is considered to be ≥ 0.5 points from baseline.[5] The MCID for daytime or nighttime rescue medication use is a decrease of 0.81 puffs/day.

Potential harms include periprocedural risk and risk for exacerbation of asthma during the treatment phase.

Short-term results are evaluated from weeks post-treatment to 12 months. Long-term follow-up studies have evaluated patients receiving bronchial thermoplasty up to 10 years posttreatment.

Study Selection Criteria

We selected methodologically credible studies, following these principles.

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with preference for RCTs;
- To assess longer term outcomes and adverse effects, we sought single-arm studies that capture longer periods of follow up and/or larger populations.
- Within each category of study design, we preferred larger sample size studies and longer duration studies.
- We excluded studies with duplicative or overlapping populations.

For conditions such as asthma, where there are subjective outcomes such as self-reported symptoms and frequency of as-needed medication, placebo- or sham-controlled randomized trials are needed to demonstrate that the intervention has a benefit beyond the placebo effect.

Review of Evidence

Randomized Controlled Trials

There are 3 industry-sponsored RCTs that have evaluated the efficacy and safety of bronchial thermoplasty. The study characteristics and results are summarized in Tables 1 and 2. An additional small, international RCT is summarized in the text.

Research in Severe Asthma Trial

Pavord et al (2007) published the initial results of the Research in Severe Asthma (RISA) trial.[6] Participants met multiple criteria for severe uncontrolled asthma. All patients included in the study were White. After a 2-week run-in period, participants were randomized to a control group that received continued medical management alone or to medical management plus treatment with the Alair Bronchial Thermoplasty System. The primary objective of RISA was to determine the safety of bronchial thermoplasty. The rates of the procedure and post-procedure respiratory adverse events, as well as more serious adverse events (defined as any event that was fatal, required prolonged hospitalization, caused substantial immediate risk of death, resulted in permanent impairment, or required intervention to prevent permanent impairment), were recorded. No overall statistical analysis was done that compared serious adverse events in the 2 groups.

Secondary objectives included an evaluation of the effect of bronchial thermoplasty on asthma symptoms and daily medication requirements as an indication of efficacy. At 52 weeks, bronchial thermoplasty patients had a significantly greater improvement in β-agonist use than control patients (decrease of 26 puffs per week vs. 6 puffs per week, respectively, $p<.05$). There were no significant differences between groups in other efficacy variables including morning and evening peak expiratory flow, symptom scores, number of symptom-free days, percent predicted

improvement in forced expiratory volume in 1-second (FEV_1), and QOL measures. The small sample size limited the power to detect differences in the efficacy outcomes.

Pavord et al (2013) published 5-year safety data on 14 (82%) of the 17 patients randomized to bronchial thermoplasty in the RISA trial.[7] All 14 patients completed the 3-year evaluation, and 12 patients completed evaluations at 4 and 5 years. As previously described, safety outcomes were the primary outcomes of RISA. In year 1, each asthma symptom was considered an adverse event and, in subsequent years, multiple asthma symptoms were considered to be a single adverse event. Among those with follow-up data available, the number of patients with asthma adverse events in years 2, 3, 4, and 5 were 5 (36%), 7 (50%), 2 (17%), and 5 (42%), respectively. Also, during years 2 to 5, there were 11 respiratory-related hospitalizations in 5 patients. The number of patients with data available was too small to draw reliable conclusions about long-term safety, and there were no long-term data available on patients in the control group.

Asthma Intervention Research Trial

Cox et al (2007) published findings of the Asthma Intervention Research (AIR) trial, which was designed to evaluate symptom control and adverse events following bronchial thermoplasty in patients with moderate-to-severe persistent asthma.[8] Approximately 92.6% of participants were White, 4.6% of participants were Black, and 2.8% of participants were Asian. Participants were randomized to medical management with inhaled corticosteroids and LABA or to the same medical management strategy plus bronchial thermoplasty. At the end of the follow-up visits at 3, 6, and 12 months, there was a 2-week period of abstinence from LABA, during which data on exacerbations were collected. Between data collection periods, patients could use all maintenance therapies.

The primary outcome was the difference between groups in the rate of mild exacerbations from the baseline 2-week abstinence period. An exacerbation was defined as the occurrence on 2 consecutive days of a reduction in the morning peak expiratory flow of at least 20% below the average value (recorded during the week before the abstinence period), the need for more than 3 additional puffs of rescue medication compared with the week before the abstinence period, or nocturnal awakening caused by asthma symptoms. The trial was powered to detect a difference between groups of 8 mild exacerbations per person per year. Data were available at 3 months for 100 (89%) of 112 patients and at 12 months for 101 (90%) patients; all patients were included in the safety analysis.

The rate of adverse events was higher in the bronchial thermoplasty group during the active treatment period, but the proportion of adverse events was similar in the 2 groups in the posttreatment period. Posttreatment, 3 patients in the bronchial thermoplasty group required hospitalization and 2 patients in the control group required a total of 3 hospitalizations. A trial limitation is the lack of a sham intervention and, consequently, an inability to blind patients to the treatment group.

Thomson et al (2011) published 5-year data from the AIR trial.[9] All trial participants who completed the 1-year follow-up visit were invited to participate in the extension study; 45 (87%) of 52 in the bronchial thermoplasty group and 24 (49%) of 49 in the control group opted to participate. Follow-up was done on an annual basis. Patients in the control group were followed for 2 additional years, and patients in the bronchial thermoplasty group were followed for 5 years. Twenty-one (88%) of 24 patients in the control group and 42 (93%) of 45 in the bronchial thermoplasty group completed the final follow-up. No instances of pneumothorax, intubation, mechanical ventilation, cardiac arrhythmias, or death were reported during the extension study. In the first year (year 2 of the study), the rate of hospitalizations was 3 (7%) of 45 in the bronchial thermoplasty group and 0 in the control group (p=.55). In year 3, the rate of hospitalizations in the bronchial thermoplasty group was again 3 (7%) of 45, and 1 (5%) of 21 patients in the control group (p=1.00). Rates of emergency department visits in year 2 were 3 (7%) and 3 (12.5%) in the bronchial thermoplasty and control groups, respectively (p=.41); in year 3, rates were 3 (5%) and 3 (5%), respectively (p=1.00). There was 1 hospitalization each in years 4 and 5 in the bronchial thermoplasty group.

In the extension study of the AIR trial, unlike the initial follow-up period, respiratory adverse events with multiple symptoms were recorded as a single adverse event. This could give a misleading impression of the total number of adverse events or the relative number in the 2 groups. The incidence of respiratory adverse events during year 2 was 24 (53%) of 45 in the bronchial thermoplasty group and 13 (54%) of 24 in the control group. During year 3, the incidence was 24 (56%) of 43 in the bronchial thermoplasty group and 12 (57%) of 21 in the control group; differences between groups were not statistically significant in year 2 or 3. The incidence of respiratory adverse events in the bronchial thermoplasty group was similar in subsequent years; rates were 23 (53%) of 43 in year 4 and 22 (52%) of 42 in year 5.

The Thomson et al (2011) study also reported on 2 measures of lung function: post-bronchodilator FEV_1 and forced vital capacity. Exact numbers were not reported, but post-bronchodilator FEV_1 did not go below 80% of predicted in either group during years 2 to 5. The group comparisons of safety and efficacy in this follow-up trial were limited by the differential rate of follow-up between the 2 groups, with a lower percentage of patients in the control group agreeing to participate in the follow-up study.

Asthma Intervention Research 2 Trial

The Asthma Intervention Research 2 (AIR2) Trial was an RCT evaluating the efficacy of bronchial thermoplasty at 30 sites in 6 countries (including the U.S.); findings were published by Castro et al (2010).[10] Of those included in the AIR2 trial, 77.4% of participants were White, 11.8% of participants were Black, and 10.8% of participants did not have their race or ethnicity described by investigators. Unlike the other 2 RCTs, the control condition was a sham intervention, and the trial was double-blind. Eligibility criteria were similar to those in the AIR trial; key differences were that a higher initial dose of inhaled corticosteroids was required (equivalent to at least 1000 µg beclomethasone), and patients were required to have experienced at least 2 days of asthma symptoms during the 4-week baseline period and have a baseline score on the AQLQ of no more than 6.25. (The possible range of the AQLQ score is 1 to 7, with a higher number representing a better QOL). Also different from the AIR trial, patients were not required to experience symptom worsening during a period of abstinence from LABAs. Patients were stable on their asthma medication and continued their regimens during the study. The primary outcome was the difference between groups in the change from baseline in the AQLQ score, with scores from the 6-, 9-, and 12-month follow-ups averaged (integrated AQLQ score). A related outcome was the proportion of patients who achieved a change in their AQLQ score of 0.5 or greater, generally considered the minimally important difference for this scale. Bayesian analysis was used. The target posterior probability of superiority (PPS) of bronchial thermoplasty over sham was 95%, except for the primary AQLQ endpoint; there the target was 96.4% to adjust for 2 interim looks at the data. The power for the analysis was not reported in the article.

Participants and outcome assessments were blinded, but the intervention team was unblinded. The sham intervention was identical to the active treatment, except that no radiofrequency energy was delivered. Nine participants withdrew consent before beginning treatment, and 288 underwent bronchoscopy and were included in the intention-to-treat population. One hundred eighty-five participants in the treatment group and 97 in the sham control group underwent the second bronchoscopy, and the same number of patients had the third bronchoscopy (it is not clear whether they were the same patients).

The superiority of bronchial thermoplasty was not achieved in the intention-to-treat population for the primary effectiveness outcome, mean change in the integrated AQLQ score. Mean standard deviation (SD) change was 1.35 (1.10) in the bronchial thermoplasty group and 1.16 (1.23) in the sham control group. Using Bayesian analysis, the PPS was 96%. This did not surpass the target PPS of 96.4%. However, the superiority of bronchial thermoplasty on a related outcome was achieved. In the intention-to-treat population, the percentage of patients achieving an AQLQ score change of 0.5 or greater (i.e., at least the minimally important difference) was 79% in the bronchial thermoplasty

group and 64% in the control group. The PPS at 99.6% surpassed the target probability for secondary outcomes of 95%. Additional analysis of data from the active treatment group suggested that responders (defined as a change in AQLQ score of at least 0.5) were more likely to have a lower baseline score than nonresponders (mean, 4.1 vs. 5.1, respectively).

Several secondary outcomes favored bronchial thermoplasty over the sham control group. These included a reduction in the proportion of patients reporting asthma worsening during follow-up (27.3% vs. 42.9%, respectively; PPS=99.7%) and a reduction in the number of emergency department visits (0.07 vs. 0.43 visits per person per year, respectively; PPS=99.9%). Moreover, there was a reduction in severe exacerbations of 0.47 per person per year in the bronchial thermoplasty group compared with 0.70 per person per year in the control group (PPS=95.5%). There were no significant differences between groups in other secondary efficacy outcomes, including morning peak expiratory flow, the number of symptom-free days, symptom score, and rescue medication use.

For safety outcomes, during the treatment phase, there was a higher rate of respiratory adverse events in the active treatment group (85% of participants; mean, 1.0 events per bronchoscopy) compared with the sham group (76% of participants; mean, 0.7 events per bronchoscopy). A total of 16 (8.4%) patients in the active treatment group required 19 hospitalizations for respiratory symptoms during the treatment phase compared with 2 (2%) patients in the sham group, who required 1 hospitalization each. However, during the posttreatment period, 70% of patients in the bronchial thermoplasty group and 80% of patients in the sham group reported adverse respiratory events. During this phase of the trial, 5 (2.6%) patients in the bronchial thermoplasty group had a total of 6 hospitalizations for respiratory symptoms, and 4 (4.1%) patients in the sham group had 12 hospitalizations (1 patient had 9 hospitalizations).

In the AIR2 trial, the sham group had a relatively high response rate (e.g., 64% experienced a clinically significant increase in the AQLQ score). Blinding appeared to be initially successful and remained so for the sham group. Participants in both groups were unable to correctly guess their treatment group after the first bronchoscopy. During subsequent assessments, this continued among patients in the sham group, whereas in the bronchial thermoplasty group, a larger proportion guessed correctly.

Two- and 5-year follow-up data on patients in the treatment group of the AIR2 trial have been published. Castro et al (2011) reported on 2-year data in 166 (87%) of 190 patients randomized to the bronchial thermoplasty group.[11] In the second year after treatment, the proportion of participants who experienced severe exacerbations was 23.0% (95% confidence interval [CI], 16.6% to 29.5%). This compares with a 30.9% (95% CI, 24.2% to 37.7%) rate of exacerbations during year 1. The proportion who experienced asthma adverse events was 28.7% (95% CI, 22.1% to 35.3%) in year 1 and 26.5% (95% CI, 19.8% to 33.2%) in year 2. Wechsler et al (2013) reported on 5-year data for 162 patients in the AIR2 trial (85% of those randomized to the treatment group).[12] In a matched-pair analysis including the 162 study completers and the same group in previous years, the rate of severe exacerbations in years 1, 2, 3, 4, and 5 was 30.9%, 23.5%, 34.0%, 36.4%, and 21.6%, respectively. The proportion of patients experiencing severe exacerbations in years 2, 3, 4, and 5 did not differ significantly from the number of exacerbations in year 1. The proportion of patients who experienced adverse asthma events (at least 2 asthma symptoms occurring at the same time) was 28.7%, 27.9%, 29.6%, 31.4%, and 24.7%, respectively. The proportion of patients with at least 1 hospitalization for respiratory adverse events during these same years was 3.3%, 4.2%, 6.2%, 5.7%, and 1.9%, respectively. In the 12 months before bronchial thermoplasty, the rate of hospitalization for respiratory symptoms in this group was 4.2%. These follow-up studies are limited in that follow-up data were not collected on patients randomized to the sham group, and therefore, outcomes (e.g., the rate of exacerbations, the rate of hospitalizations) cannot be compared in patients who did and did not receive bronchial thermoplasty.

Chaudhuri et al (2021) reported 10-year safety and efficacy results for patients enrolled in the AIR, RISA, and AIR2 trials, including 136 (52%) patients who had received bronchial thermoplasty and 56 (33%) sham or control patients.[13] Eighteen patients in the sham/control group received bronchial thermoplasty after participation in the original trials. Median patient follow-up was 12.1 years post-treatment (range, 10.8 to 15.6 years). The primary study effectiveness endpoint was the durability of treatment effect, described as the proportion of participants with severe exacerbations during years 1 and 5 compared to the proportion of patients who experienced severe exacerbations in the 12 months preceding the 10+ year visit. No formal hypothesis testing was planned. Severe exacerbations were defined as a self-reported worsening of symptoms requiring the use of systemic corticosteroids or an increased dose of systemic corticosteroids. The primary safety endpoint was the absence of clinically significant respiratory changes, including bronchiectasis or bronchial stenosis, as confirmed by computed tomography imaging. In the year preceding the 10+ year visit, 34/136 (24%, 95% CI, 18.0 to 33.1) patients treated with bronchial thermoplasty experienced severe exacerbations, which were similar to the year 5 (22%, 95% CI, 14.8 to 29.6) and year 1 (24%, 95% CI, 17.5 to 32.6) proportions. The number of severe exacerbations per patient was significantly higher compared to year 5 (p=.044), but not significantly different compared to year 1 (p=.43). In the year preceding the 10+ year visit, severe exacerbations were experienced in 14/38 (37%, 95% CI, 21.8 to 54.0) sham or control patients compared to 12/38 (32%, 95% CI, 17.5 to 48.7) in year 1. There was no change in the rate of severe exacerbations over time in the 24 sham participants from the AIR2 trial who had baseline, 1-year, and 10-year data. Both treated and non-treated groups experienced a reduction in emergency department visits. Six (7%) AIR2 patients treated with bronchial thermoplasty developed new cases of asymptomatic bronchiectasis compared to 0 cases in the sham group at the 10-year visit. Improvements in AQLQ and ACQ scores were sustained in patients treated with bronchial thermoplasty. However, these scores were not reported for sham/control patients. Interpretation of study results is limited by recall bias and low enrollment of sham-treated patients. While bronchial thermoplasty is only recommended for use in patients with severe asthma, 26% of participants did not fulfill these criteria. Additionally, the long-term effects of treatment on clinically significant respiratory changes require further elucidation.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Pavord et al (2007)[6]; RISA	U.K., Brazil, Canada	8	2004-2006	• ≥18 years with uncontrolled asthma refractory to high-dose ICS[a] and LABA[b] • FEV_1 ≥50% predicted • Airway hyperresponsiveness[c] • Abstinence from smoking for 1 year • Smoking history ≤10 pack-years • 100% of patients were White	• 17 medical management and BT • Weeks 0 to 6: 3 treatments at least 3 weeks apart • Weeks 6 to 22: steroid stable • Weeks 22 to 36: protocol-defined steroid wean • Weeks 36 to 52: investigator-led steroid reduction	• 17 medical management alone • ICS dose tapered in 3 stages by 20% to 25% of baseline dose every 4 weeks to a minimal dose of fluticasone propionate 100 to 600 mg/d or equivalent
Cox et al (2007)[8] AIR	U.K., Brazil, Canada, Denmark	11	2002-2005	• 18 to 65 years with moderate-to-severe persistent asthma	• 56 medical management and BT (3 treatments at	• 56 medical management alone

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
				requiring daily ICS[d] and LABA[b] • FEV_1 60% to 80% of predicted • Airway hyperresponsiveness • Stable asthma 6 weeks prior to enrollment • No current or recent respiratory infection[e] • 92.6% of participants were White, 4.6% of participants were Black, and 2.8% of participants were Asian	least 3 weeks apart) • Follow-up at 3, 6, and 12 months,[f] then 2-week LABA abstinence	• Follow-up at 3, 6, and 12 months,[f] then 2-week LABA abstinence
Castro et al (2010)[10]; AIR2	U.S., EU, Canada, Australia	30	2000-2015	• ≥2 day asthma symptoms during a 4-week baseline required high initial dosage of ICS[g] • Baseline AQLQ score ≤6.25 • 77.4% of participants were White, 11.8% of participants were Black, and 10.8% of participants did not have their race or ethnicity described	• 196 received BT (3 treatments at least 3 weeks apart)	• 101 received sham procedure

AIR: Asthma Intervention Research Trial; AQLQ: Asthma Quality of Life Questionnaire; BT: bronchial thermoplasty; FEV1: forced expiratory volume at 1 second; ICS: inhaled corticosteroids; LABA: long-acting ß-agonist; RCT: randomized controlled trial; RISA: Research in Severe Asthma.

[a] Treatment of fluticasone propionate ≥750 µg/d or equivalent.

[b] Treatment of salmeterol ≥100 µg/d or equivalent.

[c] Demonstrated by challenge with methacholine or reversible bronchoconstriction during prior 12 mo.

[d] Treatment of beclomethasone ≥200 µg or equivalent.

[e] No more than 2 respiratory infections requiring treatment in past year and required to undergo a 2-wk baseline test period without LABAs; eligibility depended on worsening asthma control during that time.

[f] Between data collection periods, patients could use all maintenance therapies.

[g] Treatment of beclomethasone ≥1000 µg or equivalent.

Table 2. Summary of Key RCT Results

Study	Respiratory AE (No. of Events)	Serious AE (Hospitalization)[b]	Reduction in SABA (Puffs per 7 days)[c]	% Reduction in OCS Dosed[d]	% Reduction in ICS Dosed[d]
Pavord et al (2007)[6]; RISA					
BT (n=15)[a]	136	7	-26.6 (40.1)	63.6 (45.4)	28.6 (30.4)
MM (n=17)	57	0	-1.5 (11.7)	26.2 (40.7)	20 (32.9)
Effect (95% CI); p			NR (NR); <.05	NR (NR);.12	NR (NR);.059
	Change in Rate of Exacerbations[e]				

Study	Respiratory AE (No. of Events)	Serious AE (Hospitalization)[b]	Reduction in SABA (Puffs per 7 days)[c]	% Reduction in OCS Dosed[d]	% Reduction in ICS Dosed[d]
Cox et al (2007)[8]; AIR					
BT (n=52)[f]					
Baseline	0.35 (0.32)				
12 months	0.18 (0.31)				
MM (n=49)[f]					
Baseline	0.28 (0.31)				
12 months	0.31 (0.41)				
Effect (95% CI); p	NR (NR);.03				
	Change in AQLQ[h]				
Castro et al (2010)[10]; AIR2					
BT (n=190)[g]					
Baseline	4.30 (1.17)				
12 months	5.66 (1.06)				
Mean change	1.35 (1.10)				
BT sham (n=98)[g]					
Baseline	4.31 (1.21)				
12 months	5.48 (1.15)				
Mean change	1.16 (1.23)				

AE: adverse events; AIR: Asthma Intervention Research Trial; AQLQ: Asthma Quality of Life Questionnaire; BT: bronchial thermoplasty; CI: confidence interval; ICS: inhaled corticosteroid; MM: medical management; NR: not reported; OCS: oral corticosteroid; RCT: randomized controlled trial; RISA: Research in Severe Asthma; SABA: short-acting β-agonist.

[a] There were 2 withdrawals from BT group prior to first treatment.

[b] There were no deaths or serious AEs other than hospitalization related to respiratory events in either group.

[c] Results at 22 wks.

[d] Results at 52 wks.

[e] Change from baseline in mean number of mild exacerbations per subject per week at 12 mo.

[f] Analyses based on participants available for evaluation at 12 mo.

[g] Intention-to-treat analyses based on participants who underwent at least 1 bronchoscopy procedure in either arm.

[h] Change from baseline in integrated AQLQ score at 12 months with higher score (0 to 7) indicating better quality of life. A score change of ≥0.5 defines minimal important difference.

Leroux et al (2024) published an additional small, international (France), single-center, single-blind RCT evaluating bronchial thermoplasty in patients with severe asthma.[14] The trial randomized 30 patients with severe asthma (GINA step 5) who had experienced ≥4 severe exacerbations in the preceding year to receive either bronchial thermoplasty (3 treatments over the course of 3 months; n=15) or control treatment (usual care *without* sham procedure; n=15). The primary outcome was the number of severe exacerbations 12 months following the intervention (i.e., 15 months from inclusion). At baseline, patients in the bronchial thermoplasty group were younger (mean, 46.1 years vs 53.2 years in the control group; p=.046). Respiratory function was similarly impaired in both groups, with a median FEV1% of 61.0% in the bronchial thermoplasty group and 64.0% in the control group. Mean daily oral corticosteroid use was 9.33 mg in the bronchial thermoplasty group and 11 mg in the control group. In the year prior to enrollment, patients in the bronchial thermoplasty group had an average of 5 severe exacerbations, compared with 6 among controls. Results demonstrated a 27% reduction in severe exacerbations in the bronchial thermoplasty group, which experienced a mean of 6.09 severe exacerbations over 15 months, compared with 8.28 in the control group (0.73-fold; 95% CI, 0.56 to 0.97; p=.039). Additionally, a 32% reduction in daily oral corticosteroid use was also seen in the bronchial thermoplasty group, with patients receiving an average of 8.18 mg/day compared with 12.04 mg/day in the control group (p=.0163). Although the bronchial thermoplasty group showed a mean decrease in corticosteroid dose of 4.60 mg/day, and the control group an increase of 1.67

mg/day, this between-group difference was not statistically significant (p=.219). Lastly, a greater improvement in asthma-related quality of life was reported in the bronchial thermoplasty group, with a mean change in AQLQ score from Visit 1 to Visit 5 of 1.19 compared with 0.24 in the control group (p=.027). At Visit 5, mean AQLQ scores were 4.05 in the bronchial thermoplasty group and 3.56 in the control group (p=.30). During treatment, 46 respiratory events occurred in 39 procedures, mostly within 1 day and resolving within 7 days. Increased sputum was most common (25.6%).

Post-U.S. Food and Drug Administration Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma

Post-U.S. Food and Drug Administration Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma (PAS2) is an open-label, nonrandomized trial of the Alair system, required for post premarket approval. Chupp et al (2017) compared 3-year follow-up results from 190 patients in the AIR2 trial with a subgroup (n=190) from PAS2.[15] Of those enrolled, 168 patients from PAS2 reached 3 years of follow-up and were compared with 165 patients from AIR2 who also had 3 years of follow-up. The primary outcome was comparing the incidence of severe exacerbation in each trial. In the 12 months before treatment, 74.2% of patients from PAS2 experienced severe exacerbations, which decreased significantly during the third year of follow-up to 39.9% (p<.001). A similar reduction was observed in AIR2 patients, with the incidence of severe exacerbations decreasing to 36.8%. Similar decreases in emergency department visits occurred in both groups when year 3 was compared with the 12 months before treatment (PAS2, 55% reduction; AIR2, 72.3% reduction; p<.001); the incidence of hospitalization also decreased for both groups. In the first and second years after treatment, the incidence of hospitalization in PAS2 decreased to 14.4% and 12.7%, respectively; the incidence of emergency department visits decreased to 18.3% in the first year and 13.5% in the second year after treatment. Overall, patients from PAS2 showed improved results comparable to those observed in AIR2; however, there were a number of differences between the trials that limited conclusions. At baseline, patients enrolled in AIR2 had better asthma control than those in PAS2; PAS2 was restricted to North America, and different definitions of severe exacerbations were used in each trial.

The 5-year follow-up results for the full PAS2 cohort are described in a study by Chupp et al (2022).[16] Of the 284 individuals enrolled in PAS2, 227 (81%) completed 5 years of follow up; 84% of individuals included were White, 9% Black or African heritage, 3% Hispanic or Latino, 1.4% Asian, 1% American Indian or Alaska native, and 1.6% from other racial or ethnic groups that were not described by investigators. Of note, a larger proportion of the 52 individuals who were not followed for 5 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 bronchial thermoplasty compared with the 227 individuals followed for 5 years, indicating that those who dropped out of PAS2 may have had more serious disease and were not included in the analysis. By year 5 posttreatment, the proportion of individuals with severe exacerbations was significantly lower at 42.7%, compared with 77.8% in the 12 months prior to treatment (p<.001). There was also a significant reduction in severe exacerbations from baseline (1.61 exacerbations/individual) to 5 years posttreatment (0.72 exacerbations/individual; p<.001). Emergency department visits and hospitalizations were also significantly decreased by 5 years compared to 12 months prior to treatment, from a rate of 29.4% to 7.9% (p<.001) and 16.1% to 4.8% (p=.0003), respectively. At year 5 after bronchial thermoplasty, annual hospitalization rates fell from 0.22 hospitalizations per individual at baseline to 0.06 hospitalizations per individual (p=.0012). Bronchial thermoplasty did not alter spirometric parameters as reported in previous studies, but did reduce asthma maintenance medication use. The mean daily dose of inhaled corticosteroids (beclomethasone or equivalent) was reduced from 2272 µg/d at baseline to 1928 µg/d by year 5. The number of individuals on maintenance oral corticosteroids decreased from 19.4% at baseline to 9.7% at 5 years. Clinical improvement was statistically significant across all subgroup analyses, regardless of baseline eosinophil and neutrophil counts. These results are limited by the lack of a comparator arm, increased drop-out rates of those with more severe asthma, lack of long-term QOL scores, and lack of response comparison between bronchial thermoplasty and standard of care medications.

Registries

Reports from the U.K. Severe Asthma Registry (UKSAR) and the Bronchial Thermoplasty Global Registry (BTGR) are described in Tables 3 and 4. All UK centers performing bronchial thermoplasty provide data to the UKSAR registry.

Burn et al (2017) reported on the safety outcomes of bronchial thermoplasty in the U.K.[17] The analysis combined data from 2 sources, UKSAR and the Hospital Episode Statistics warehouse. For 59 patients, data in the 2 databases could be matched and were used to calculate event rates for 4 binary safety outcomes. Procedural complications were reported in 17 (11%) of 152 procedures in 13 (22%) patients; emergency department readmissions within 30 days of the initial hospitalization were reported for 15 (11.8%) patients; and accident and emergency visits (i.e., emergency department) for any reason were reported for 13 (8.6%) patients. For the fourth outcome (postprocedure overnight stay), 70 (46.1%) of 152 procedures were followed by an overnight stay. In total, 20.4% of procedures in the matched cohort were associated with at least 1 of the 4 safety issues. The authors noted that the relatively high rate of safety events might have been related to older patients with more severe disease being treated in clinical practice compared with patients included in clinical trials.

Efficacy and safety data from the UKSAR registry were subsequently reported by Burn et al (2019).[18] Efficacy data were available for 86 patients with at least 1 follow-up visit. Safety data were available for 131 patients, including the 59 in the previous report. Follow-up data up to 60 months were recorded with counts of adverse events annualized to compare rates before and after bronchial thermoplasty. Comparison of the first year post-treatment with pre-procedure baseline showed a statistically and clinically significant improvement in the AQLQ of 0.75 (p<.001) and EuroQoL-5D, but there was no significant improvement in other outcome measures when adjusted for multiple comparisons. There were trends for a decrease in unscheduled healthcare visits (-0.93, p=.050) and in hospital admissions in the year after bronchial thermoplasty (-2.0, p=.056). There was no significant change in mean FEV_1 at 12 or 24 months. Because of the strong placebo effects noted in the controlled trials, interpretation of subjective quality of life measures is limited.

The BTGR is a prospective, open-label, multicenter study across 18 centers in Spain, Italy, Germany, the UK, the Netherlands, the Czech Republic, South Africa, and Australia that enrolls adults indicated for and treated with bronchial thermoplasty. Torrego et al (2021) reported on the 2-year outcomes from the BTGR.[19] One hundred fifty-seven adults were included in the registry at 2 years. Racial and ethnic demographics of participants were not described. A comparison of the proportion of individuals experiencing asthma events during the 12 months prior to bronchial thermoplasty to the 2-year follow-up showed a reduction in severe exacerbations requiring corticosteroids (90.3% vs. 56.1%; p<.0001), emergency department visits (53.8% vs. 25.5%; p<.0001), and hospitalizations (42.9% vs. 23.5%; p=.0019). Asthma Control Questionnaire and AQLQ scores improved from 11.18 and 3.26 at baseline to 15.54 and 4.39 at 2 years, respectively (p<.0001 for both). The registry results were limited by a lack of a comparator arm, a high attrition rate, with approximately one-third of individuals dropping out, and variation in investigator experience with bronchial thermoplasty between clinical sites.

Table 3. Summary of Registry Study Characteristics

Study	Study Type	Registry	Dates	Participants	Treatment	Follow-Up
Burn et al (2017) [17]	Registry	UKSAR and Hospital Episode Statistics warehouse	2011-2015	59 patients who received bronchial thermoplasty and had data in both UKSAR and the Hospital Episode Statistics database. Race and ethnicity of participants were not described.	3 bronchial thermoplasty sessions	30 days

Study	Study Type	Registry	Dates	Participants	Treatment	Follow-Up
Burn et al (2019)[18]	Registry	UKSAR	2011-2016	133 patients who received bronchial thermoplasty and consented to be in the UKSAR Registry. Race and ethnicity of participants were not described.	At least 1 bronchial thermoplasty session	6 mo to 5 yr
Torrego et al (2021)[19]	Registry	BTGR	2014-2019	157 adult patients who received bronchial thermoplasty and consented to be in the BTGR. Race and ethnicity of participants were not described.	3 bronchial thermoplasty sessions	up to 24 months

BTGR: Bronchial Thermoplasty Global Registry; UKSAR: U.K. Severe Asthma Registry.

Table 4. Summary of Registry Study Results

Study	AQLQ	ACQ	EQ-5D	Rescue Steroid	Procedural Complications	Overnight Stay	Unscheduled or Emergency Department Visits	Hospital admissions
Burn et al (2017)[17]					17 (11%) of procedures	70 (46.1%) of procedures	13 (8.6%) of patients	15 (11%) of patients
Burn et al (2019)[18]								
Change from baseline (p-value)	0.75 (<.001)	-0.43 (.083)	.008 (.909)	-0.26 (.307)			-0.93 (.050)	-2.0 (.056)
Torrego et al (2021)[19]					**Respiratory AEs; Serious respiratory AEs**			
12 months prior to BT	3.26	11.18	NR	90.3%	During treatment period: 45.2%; 28%	NR	53.8%	42.9%
2-years post BT	4.39	15.54	NR	56.1%	0%; 0%	NR	25.5%	23.5%
p-value	<.0001	<.0001		<.0001			<.0001	.0019

AE: adverse events; AQLQ: Asthma Quality of Life Questionnaire; ACQ: Asthma Control Questionnaire; BT: bronchial thermoplasty; EQ-5D: EuroQol-5D; NR: not reported.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2014. Input was mixed on whether bronchial thermoplasty is considered investigational for the treatment of asthma; 3 reviewers agreed with this statement and 2 reviewers disagreed. Reviewers who disagreed tended to use bronchial thermoplasty in patients who had not responded to other treatments and who did not think there were treatment alternatives.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Chest Physicians

In May 2014, the American College of Chest Physicians posted a position statement on coverage and payment for bronchial thermoplasty.[20] The document stated in part:

> "...bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment and, therefore should not be considered experimental. Randomized controlled clinical trials of bronchial thermoplasty for severe asthma have shown a reduction in the rate of severe exacerbations, emergency department visits, and days lost from school or work. Additionally, data published in December 2013 demonstrates the persistence of the reduction in asthma symptoms achieved by bronchial thermoplasty for at least 5 years..." The position statement references the 5-year follow-up data from the AIR2 trial (Wechsler, 2013), stating the reported outcomes further demonstrate the "safety, effectiveness, and durability" of bronchial thermoplasty.

Global Initiative for Asthma

Global Initiative for Asthma (GINA) is an international network of organizations and professionals with expertise in asthma. The group has been updating a report entitled *Global Strategy for Asthma Management and Prevention* annually since 2002; the most recent update was issued in 2024.[5] The organization has recommended stepped care for the treatment of asthma. Step 5 options for patients with uncontrolled symptoms and/or exacerbations include referral for phenotypic investigation and potential add-on treatment. Bronchial thermoplasty may be considered as an add-on treatment in adults with severe asthma that remains uncontrolled despite optimization of asthma therapy and referral to a severe asthma specialty center. GINA notes that bronchial thermoplasty should only be administered in the context of a systematic registry or a clinical study, as the evidence for efficacy and long-term safety is limited.

A guide for the diagnosis and management of difficult-to-treat and severe asthma was first published in 2019; the most recent update was issued in 2024.[21] For patients whose asthma remains uncontrolled despite GINA step 4 or 5 treatment with no evidence of type 2 inflammation (i.e., medium- or high-dose inhaled corticosteroids and long-acting ß-agonists), treatment options include a trial of a long-acting muscarinic agent (LAMA), low-dose azithromycin, interleukin-4 receptor antagonist (dupilumab), or anti-thymic stromal lymphoprotein (tezepelumab). Oral corticosteroids are considered as a last resort. Bronchial thermoplasty with registry enrollment may also be considered for patients who do not respond to type 2-targeted biologic therapy. The guidance notes that the evidence for the efficacy and long-term safety of bronchial thermoplasty is limited.

National Asthma Education and Prevention Program

In 2020, the National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) Expert Panel Working Group published focused updates to the National Heart, Lung, and Blood Institute's guidelines for the diagnosis and management of asthma. This update was based on prior systematic reviews of the evidence published by the Agency for Healthcare Research and Quality.[22,23]

The following conditional recommendation based on low certainty evidence on the use of bronchial thermoplasty was issued:

- "In individuals ages 18 years and older with persistent asthma, the Expert Panel conditionally recommends against bronchial thermoplasty.
- Individuals ages 18 years and older with persistent asthma who place a low value on harms (short-term worsening symptoms and unknown long term side effects) and a high value on potential benefits (improvement in quality of life, a small reduction in exacerbations) might consider bronchial thermoplasty."

For patients who opt to choose this intervention via shared decision-making, the panel recommends that clinicians offer the procedure in the setting of a clinical trial or registry study to facilitate the collection of long-term outcomes.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2018) published guidance on bronchial thermoplasty for severe asthma.[24] The guidance stated: "Current evidence on the safety and efficacy on bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." It was also noted that "further research should report details of patient selection and long-term safety and efficacy outcomes."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03765307[a]	Safety and Efficacy of the SyMap Bronchial Ablation System for Treatment of Severe Asthma: A Prospective, Multicenter, Randomized Controlled Clinical Trial (Bronchial Ablation for Treatment of Asthma (BATA) Trial)	160	Dec 2028
NCT03435237	Phenotyping Asthma for Bronchial Thermoplasty: Airway Smooth Muscle Structure and Function	50	Dec 2024 (recruiting)
NCT04077528	Research on Severe Asthma (RAMSES)	2000	Sep 2025 (recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	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
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2025	New policy.
06/01/2026	Administrative update. Definitions of Decision Determinations section updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

Below is an excerpt of the language taken from California Children's Services Numbered Letter 05-1020.*

*Department of Healthcare Services Numbered Letter 05-1020. Accessed April 21, 2026, from https://www.dhcs.ca.gov/services/ccs/Documents/CCS-NL-05-1020-Experimental-and-Investigational-Services.pdf

Policy

A. The California Children's Services (CCS) Program and the Genetically Handicapped Persons Program (GHPP) will not provide coverage for experimental services unless specifically authorized by law.
B. The CCS Program and GHPP may provide coverage for an investigational service if:
    1. It is approved by the FDA under any Investigational New Drug (IND) Application; or
    2. It is authorized for use under the State of California's Right to Try Act; and
    3. Its use is consistent with its FDA-approved IND Application or the State of California's Right to Try Act;
C. Additional criteria that will be considered in the adjudication process include:
    1. Conventional therapy will not adequately treat the intended patient's condition;
    2. Conventional therapy will not prevent progressive disability or premature death;
    3. The provider of the proposed service has a record of safety and success with it or equivalent to that of other providers of the investigational services;
    4. Other criteria (e.g., cost and availability) may be considered in the adjudication of a given request in cases in which more than one investigational service is available;
    5. There is reasonable expectation that the investigational service will significantly prolong the patient's life or will maintain or restore a range of physical and social function suited to activities of daily living; and
    6. The service is not being performed as part of a research study protocol. For a beneficiary with cancer who participates in a clinical trial for cancer, California Health and Safety

Code (HSC) § 1370.6 requires that all routine patient care costs related to the clinical trial be covered if the beneficiary's CCS-paneled treating physician recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. The coverage does not include investigational services that have not been approved by the FDA and that are associated with the clinical trial.

Feedback

Blue Shield of California Promise Health Plan is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.