



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers bronchial thermoplasty for the treatment of asthma to be **investigational**.*

Background/Overview

Asthma

Asthma, a chronic lung disease, affects approximately 8.0% of adults and 6.5% of children in the United States (U.S.). 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. 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. 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 2020 and 2021, asthma exacerbations accounted for approximately 1.2 million emergency department visits and 3517 deaths overall, respectively. 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. 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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

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. The preferred daily medications: step 1: short-acting β -agonists as-needed; step 2: low-dose inhaled corticosteroids (ICS); step 3: ICS and long-acting β -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 (ie, steps 5 and 6 in the stepwise approach to care).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

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: OOO.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Bronchial thermoplasty is a potential treatment option for patients 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

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 (ie, procedural complications, emergency respiratory readmissions, emergency department visits, and/or post procedure 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.

Supplemental Information

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 US professional society, an international society with US

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

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. 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..."

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 2022. The organization has recommended stepped care for 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, with a goal to update annually. The updated guidance has not yet been released to the public, but a slide set from GINA highlighting decision trees from the guidance, updated in May 2022, is available on their website. For patients whose asthma remains uncontrolled despite GINA step 4 or 5 treatment with no evidence of type 2 inflammation (ie, medium- or high-dose inhaled corticosteroids and long-acting β -agonists), treatment options include a trial of tiotropium or

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

macrolide if not already tried, low-dose oral corticosteroids, and consideration of bronchial thermoplasty with registry enrollment. 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.

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. 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."

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266
Original Effective Date: 07/21/2010
Current Effective Date: 10/09/2023

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 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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 2023 2022 (recruiting)
NCT02464995	Bronchial Thermoplasty in Severe Asthma With Frequent Exacerbations (THERMASCORT)	34	Nov 2022 (recruiting)
NCT03435237	Phenotyping Asthma for Bronchial Thermoplasty: Airway Smooth Muscle Structure and Function	50	Dec 2023 2022 (recruiting)
NCT02975284	TASMA Extension Study: Long Term Efficacy and Safety of Bronchial Thermoplasty in Severe Asthma	30	Sep 2024 (ongoing)
NCT04077528	Research on Severe Asthma (RAMSES)	2000	Jun 2025 (recruiting)



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT01185275	A Prospective Observational Study of Biopredictors of Bronchial Thermoplasty Response in Patients With Severe Refractory Asthma (BTR Study)	133	Oct 2019

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

- Centers for Disease Control & Prevention, National Center for Health Statistics. Asthma. Updated January 2023; <https://www.cdc.gov/nchs/fastats/asthma.htm>.
- National Center for Health Statistics. Health, United States, 2019: Figure 010. 2021. <https://www.cdc.gov/nchs/health-us/content/2019.htm>.
- Asthma and Allergy Foundation of America. Asthma Disparities in America: A Roadmap to Reducing Burden on Racial and Ethnic Minorities. 2020. aafa.org/asthmadisparities.
- National Heart Lung and Blood Institute. Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2012; <https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma>.
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022; <https://ginasthma.org/wp-content/uploads/2022/05/GINA-Main-Report-2022-FINAL-22-05-03-WMS.pdf>.
- Pavord ID, Cox G, Thomson NC, et al. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. *Am J Respir Crit Care Med*. Dec 15 2007; 176(12): 1185-91. PMID 17901415
- Pavord ID, Thomson NC, Niven RM, et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. *Ann Allergy Asthma Immunol*. Nov 2013; 111(5): 402-7. PMID 24125149
- Cox G, Thomson NC, Rubin AS, et al. Asthma control during the year after bronchial thermoplasty. *N Engl J Med*. Mar 29 2007; 356(13): 1327-37. PMID 17392302

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

9. Thomson NC, Rubin AS, Niven RM, et al. Long-term (5 year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med.* Feb 11 2011; 11: 8. PMID 21314924
10. Castro M, Rubin AS, Laviolette M, et al. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. *Am J Respir Crit Care Med.* Jan 15 2010; 181(2): 116-24. PMID 19815809
11. Castro M, Rubin A, Laviolette M, et al. Persistence of effectiveness of bronchial thermoplasty in patients with severe asthma. *Ann Allergy Asthma Immunol.* Jul 2011; 107(1): 65-70. PMID 21704887
12. Wechsler ME, Laviolette M, Rubin AS, et al. Bronchial thermoplasty: Long-term safety and effectiveness in patients with severe persistent asthma. *J Allergy Clin Immunol.* Dec 2013; 132(6): 1295-302. PMID 23998657
13. Chaudhuri R, Rubin A, Sumino K, et al. Safety and effectiveness of bronchial thermoplasty after 10 years in patients with persistent asthma (BT10+): a follow-up of three randomised controlled trials. *Lancet Respir Med.* May 2021; 9(5): 457-466. PMID 33524320
14. Chupp G, Laviolette M, Cohn L, et al. Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies. *Eur Respir J.* Aug 2017; 50(2). PMID 28860266
15. Chupp G, Kline JN, Khatri SB, et al. Bronchial Thermoplasty in Patients With Severe Asthma at 5 Years: The Post-FDA Approval Clinical Trial Evaluating Bronchial Thermoplasty in Severe Persistent Asthma Study. *Chest.* Mar 2022; 161(3): 614-628. PMID 34774528
16. Burn J, Sims AJ, Keltie K, et al. Procedural and short-term safety of bronchial thermoplasty in clinical practice: evidence from a national registry and Hospital Episode Statistics. *J Asthma.* Oct 2017; 54(8): 872-879. PMID 27905828
17. Burn J, Sims AJ, Patrick H, et al. Efficacy and safety of bronchial thermoplasty in clinical practice: a prospective, longitudinal, cohort study using evidence from the UK Severe Asthma Registry. *BMJ Open.* Jun 19 2019; 9(6): e026742. PMID 31221880
18. Torrego A, Herth FJ, Munoz-Fernandez AM, et al. Bronchial Thermoplasty Global Registry (BTGR): 2-year results. *BMJ Open.* Dec 16 2021; 11(12): e053854. PMID 34916324
19. American College of Chest Physicians (ACCP). Position Statement for Coverage and Payment for Bronchial Thermoplasty. 2014; <http://www.chestnet.org/News/CHEST-News/2014/05/Position-Statement-for-Coverage-and-Payment-for-Bronchial-Thermoplasty>.
20. Global Initiative for Asthma (GINA). Diagnosis and management of difficult-to-treat & severe asthma [V4]. May 2022; <https://ginasthma.org/severeasthma/>.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

21. Cloutier MM, Baptist AP, Blake KV, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. Dec 2020; 146(6): 1217-1270. PMID 33280709
22. D'Anci KE, Lynch MP, Leas BF, et al. Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 Dec. Report No.: 18-EHC003-EF. PMID: 29659226.
23. National Institute for Health and Care Excellence. Bronchial thermoplasty for severe asthma. Interventional procedures guidance [IPG635]. 2018 <https://www.nice.org.uk/guidance/ipg635>.

Policy History

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

07/01/2010	Medical Policy Committee review
07/21/2010	Medical Policy Implementation Committee approval. New policy.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/08/2016	Medical Policy Committee review

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

09/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	31660, 31661
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Bronchial Thermoplasty for Asthma (Alair®)

Policy # 00266

Original Effective Date: 07/21/2010

Current Effective Date: 10/09/2023

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.