

**Policy: MP250**

**Section: Medical Benefit Policy**

**Subject: Bronchial Thermoplasty**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

**I. Policy:** Bronchial Thermoplasty

**II. Purpose/Objective:**

To provide a policy of coverage regarding Bronchial Thermoplasty

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

#### **DESCRIPTION:**

Bronchial Thermoplasty is a procedure believed to treat severe persistent asthma in patients whose asthma is not well controlled with conventional drug therapy. The procedure uses thermal energy (radiofrequency) to reduce airway smooth muscle mass to reduce the airway's ability to constrict. Bronchial thermoplasty is delivered in a series of three treatment sessions with a recovery period of three weeks or longer between sessions. Researchers believe that the less constriction in the airways could lead to reduced severity and frequency of asthma symptoms.

#### **REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR or Designee**

#### **COMMERCIAL BUSINESS SEGMENT**

Bronchial Thermoplasty may be considered medically necessary on a "per-case" basis for members who meet all of the following criteria:

- The member is 18 years of age or older; and
- A diagnosis of severe, persistent asthma has been established; and
- The member has documented inadequate asthma control with current maximized inhaled corticosteroids and long acting beta agonists; and
- The member is a non-smoker or has not smoked for at least one year; and
- The member has failed, is intolerant to, or is not a candidate for anti-IgE therapy or anti-Interleukin (Il)-5 therapy; and
- The member has been managed by and bronchial thermoplasty is recommended by an asthma specialist (eg, pulmonologist or allergist/immunologist)

#### **Medicare Business Segment**

CMS has assigned a transitional "pass-through" status to the codes assigned to the procedure of bronchial thermoplasty and the specialized catheter used for this procedure during the bronchoscopy. Coverage will be limited to treatment of severe persistent asthma in patients whose asthma is not well controlled with conventional drug therapy.

#### **Medicaid Business Segment**

Bronchial Thermoplasty may be considered on a "per-case" basis through the Program Exception process.

#### **EXCLUSIONS:**

The Plan does NOT provide coverage for Bronchial Thermoplasty in excess of the single three-session regimen because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the safety and effectiveness of repeat treatment beyond the single three-session protocol.

The Plan does **NOT** provide coverage for uses of Bronchial Thermoplasty other than the treatment of severe, persistent, treatment-refractory asthma because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this modality on health outcomes when compared to established tests or technologies.

#### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

#### **CODING ASSOCIATED WITH:** Bronchial Thermoplasty

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

- 31899** Unlisted procedure, trachea, bronchi  
**94799** Unlisted pulmonary service or procedure  
**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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

#### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

#### **REFERENCES:**

Geisinger Technology Assessment Committee. Bronchial Thermoplasty. January 11, 2012

American Thoracic Society. Novel therapies for asthma explored. ATS Daily Bulletin. May 18, 2010. Available at: <http://conference.thoracic.org/files/pdfs/05-18-10.pdf>. Accessed December 2010

Asthmatx website. Available at: <http://www.asthmatx.com/>. Accessed December 2010

Castro M, Rubin AS, Laviolette M, et al.; AIR2 Trial Study Group. Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, doubleblind, sham-controlled clinical trial. Am J Respir Crit Care Med. 2010 Jan 15;181(2):116-24.

Cox G, Thomson NC, Rubin AS, et al.; AIR Trial Study Group. Asthma control during the year after bronchial thermoplasty. N Engl J Med. 2007 Mar 29;356(13):1327-37.

Cox G, Miller JD, McWilliams A, et al. Bronchial thermoplasty for asthma. Am J Respir Crit Care Med. 2006 May 1;173(9):965-9.

ECRI Institute. Health Technology Forecast. Bronchial thermoplasty for the treatment of asthma. September 2007; updated April 2010.

ECRI Institute. Hotline Response. Bronchial thermoplasty for treatment of asthma. March, 2010.

Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. <https://ginasthma.org/>. Published 2022.

National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), National Heart, Lung, and Blood Advisory Council Asthma Expert Working Group. Asthma management guidelines. National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI) 2020. Focused updates <https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates>

Pavord ID, Cox G, Thomson NC, et al.; RISA Trial Study Group. Safety and efficacy of bronchial thermoplasty in symptomatic, severe asthma. Am J Respir Crit Care Med. 2007 Dec 15;176(12):1185-91.

Wechsler ME. Bronchial thermoplasty for asthma: a critical review of a new therapy. Allergy Asthma Proc. 2008 Jul-Aug;29(4):365-70.

Cayetano KS, Chan AL, Albertson TE, Yoneda KY. Bronchial thermoplasty: a new treatment paradigm for severe persistent asthma. Clin Rev Allergy Immunol. 2012 Aug;43(1-2):184-93

Chung, KF, Wenzel, SE, Brozek, JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2013.

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. 2013 Dec;132(6):1295-302.

Torrego A, Sola I, Munoz AM et al. Bronchial thermoplasty for moderate or severe persistent asthma in adults. Cochrane Database Syst Rev 2014; 3:CD009910

Pavord ID, Thomson NC, Niven RM et al. Safety of bronchial thermoplasty in patients with severe refractory asthma. *Ann Allergy Asthma Immunol* 2013; 111(5):402-7.

Iyer VN, Lim KG. Bronchial thermoplasty: Reappraising the evidence (or lack thereof). *Chest*. 2014;146(1):17-21.

Kaukel P, Herth FJ, Schuhmann M. Bronchial thermoplasty: Interventional therapy in asthma. *Ther Adv Respir Dis*. 2014;8(1):22-29.

Doeing DC, Mahajan AK, White SR, et al. Safety and feasibility of bronchial thermoplasty in asthma patients with very severe fixed airflow obstruction: A case series. *J Asthma*. 2013a;50(2):215-218.

Doeing DC, Husain AN, Naureckas ET, et al. Bronchial thermoplasty failure in severe persistent asthma: A case report. *J Asthma*. 2013b;50(7):799-801.

Kane B, Fowler SJ, Niven R. Refractory asthma -- beyond step 5, the role of new and emerging adjuvant therapies. *Chron Respir Dis*. 2015;12(1):69-77.

National Heart Lung & Blood Institute (NHLBI), Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Vancouver, WA: Global Initiative for Asthma (GINA); April 2015

Canadian Agency for Drugs and Technologies in Health (CADTH). Bronchial thermoplasty for severe asthma: A review of the clinical and cost-effectiveness, and guidelines. Rapid Response Report.; August 27, 2015.

Laxmanan B, Egressy K, Murgu SD, et al. Recent advances in chest medicine: Advances in bronchial thermoplasty. *Chest*. 2016 Mar 19

PA Dept. of Human Services, Managed care Operations Memorandum, Technology Assessment Group, OPS#11/2017-021 Nov.9, 2017

Wenzel S. Treatment of severe asthma in adolescents and adults. UpToDate . 01/30/2017

ChuppG, Laviolette M, 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* 2017; 50: 1700017

Menzella F, Galeone C, et al. Innovative treatments for severe refractory asthma: how to choose the right option for the right patient? *J Asthma and Allergy* 2017;10:237-247.

Minami D, Ando C, Nakasuka T, et al. Usefulness of bronchial thermoplasty for patients with a deteriorating lung function. *Intern Med*. 2018;57(1):75-79.

Thomson NC. Bronchial thermoplasty as a treatment for severe asthma: Controversies, progress and uncertainties. *Expert Rev Respir Med*. 2018;12(4):269-282.

Nagano N, Iikura M, Ito A, et al. Bronchial thermoplasty for severe asthma with mucus hypersecretion. *Intern Med*. 2019 ;58(11):1613-1616.

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*. 2019;9(6):e026742.

Hall CS, Quirk JD, Goss CW, et al. Single-session bronchial thermoplasty guided by 129 Xe magnetic resonance imaging. A pilot randomized controlled clinical trial. *Am J Respir Crit Care Med*. 2020;202(4):524-534

Qiu M, Wei S, Lai Z, et al. Early radiologic and bronchoscopic changes after bronchial thermoplasty in patients with severe asthma. *Exp Ther Med*. 2020 Dec;20(6):278

Langton D, Banks C, Noble PB, et al. The effect of bronchial thermoplasty on airway volume measured 12 months postprocedure. *ERJ Open Res*. 2020 Nov 2;6(4):00300-2020.

Vijayan K, Karakattu SM, Bansal A, et al. Immediate complications and flow volume changes during treatment phases of bronchial thermoplasty: A single-center descriptive study. *J Asthma*. 2021 May 18

Chaudhuri R, Rubin A, Sumino K, et al.; BT10+ Study Group. Safety and effectiveness of bronchial thermoplasty after 10 years in patients with persistent asthma (BT10+): a follow-up of three randomized controlled trials. *Lancet Respir Med*. 2021 May;9(5):457-46

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*. 2022;161(3):614-628.

Vijayan K, Karakattu SM, Bansal A, et al. Immediate complications and flow volume changes during treatment phases of bronchial thermoplasty: A single-center descriptive study. *J Asthma*. 2022;59(7):1433-1437.

Wu S, Li S, Zhang P, et al. Recent advances in bronchial thermoplasty for severe asthma: A narrative review. *Ann Transl Med*. 2022;10(6):370.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 1/11

**Revised:** 4/15 (added CMS mandate); 11/17 (added DHS program exception and commercial coverage); 11/18 (added exclusion for repeat treatment)

**Reviewed:** 2/12, 2/13; 5/16, 4/17, 12/19, 12/20, 12/21, 12/22, 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.