JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS02.13
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Bronchial Thermoplasty in the Treatment of Asthma**	*Supersedes Date*	02/01/2023
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Bronchial, Bronchial Thermoplasty, Thermoplasty

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS02.13
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD, refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) for Bronchial Thermoplasty identified (Accessed June 1, 2023)

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPD's)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database

- No Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) for Bronchial Thermoplasty identified (Accessed June 1, 2023)

For Priority Partners, (PPMCO), refer to: Code of Maryland Regulations

- No specific information located in COMAR 10.67.01-10.67.13 (Accessed June 1, 2023)

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 8.1 Respiratory System

IV. POLICY CRITERIA

A. When benefits are provided under the member's contract, JHHP may consider Bronchial Thermoplasty treatment for select patients with severe uncontrolled asthma, within the context of an Independent Institutional Review Board (IRB) approved Registry or Clinical Trial, when ALL of the following criteria are met:
   1. Adult member, 18 years of age or older, whose asthma remains uncontrolled despite high-dose inhaled glucocorticoids (ICS) and long-acting beta agonists (LABA), AND;
   2. Member has tried and failed, or is ineligible for biologic therapy, AND;
   3. Non-smoker ≥ 1 year, AND;
   4. No history of a life-threatening exacerbation, AND;
   5. Less than 3 hospitalizations for exacerbation of asthma in the previous 12 months, AND;
   6. Member is being managed by an asthma specialist, AND;
   7. Forced expiratory volume in one second (FEV1) greater than or equal to 60% of predicted

V. DEFINITIONS

Bronchial Thermoplasty Treatment: A procedure designed to reduce the smooth muscle that constricts the airway during asthma attacks. A catheter with an expandable array of electrodes is inserted in the airway via a bronchoscope which is attached to a radiofrequency generator. The electrodes are held against the bronchial walls and an electrical current is applied to generate heat that destroys the smooth muscle underneath the lining of the bronchial passages. A full course of treatment is defined as three (3) applications over a 2-3 month period (Hayes, 2016).

Severe Asthma: Asthma that remains uncontrolled despite optimized treatment with high-dose inhaled corticosteroids (ICS)-long-acting beta agonist (LABA), or that requires high-dose ICS-LABA to prevent it from becoming uncontrolled. Severe asthma must be distinguished from asthma that is difficult to treat due to inadequate or inappropriate treatment, or persistent problems with adherence or comorbidities such as chronic rhinosinusitis or obesity, as they need very different treatment compared with if asthma is relatively refractory to high-dose ICS-LABA or even oral corticosteriouds (OCS) (GINA, 2023).

VI. BACKGROUND

According to The American Academy of Allergy, Asthma, and Immunology, bronchial thermoplasty (BT) is an FDA-approved procedure for severe asthmatics 18 years of age and older, whose asthma is not well controlled with both inhaled corticosteroids and long-acting beta-agonists (AAAAI, 2021).

BT delivers thermal energy to the lung's airways which decreases the amount of smooth muscle in the lungs. As a result, the airways are less likely to constrict and the frequency of asthma attacks may be reduced (AAAAI, 2021). It takes approximately three outpatient visits, each treating a different area of the lungs, to complete the treatment. The procedure is performed during bronchoscopy and patients are under light/moderate sedation or light anesthesia and is minimally invasive (AAAAI, 2021).

In 2020 focused updates to the Asthma Management Guidelines: A report from the National Asthma Education and Prevention Program Committee Expert Panel Working Group does not recommend BT for individuals 18 years of age and older as part of routine asthma care, even if these individuals have uncontrolled asthma despite using multicomponent medical therapy, because of the small benefits-to-risk ratio. The risks of BT include asthma exacerbation, hemoptysis, and atelectasis during the treatment period. In the opinion of the Expert Panel, when BT is implemented, it should be used in settings that enroll participants in registries, ongoing clinical trials, or studies that track BT's long-term safety and effectiveness (U.S. Dept of Health and Human Services, 2020).

In the UpToDate review, Wenzel (2021) describes the risk and degree of improvement of the bronchial thermoplasty (BT) procedure for adults and adolescents. Inclusion criteria for the procedure are: patients with poorly controlled asthma despite high dose inhaled glucocorticoids and a long-acting beta agonist, nonsmoker for greater than or equal to 1 year, forced expiratory volume in one second [FEV1] greater than or equal to 60% of predicted, no history of a life-threatening exacerbation, less than 3 hospitalizations in the previous 12 months, and a willingness to accept the risk of an asthma exacerbation requiring hospitalization as a consequence of the procedure. The authors conclude that additional data are needed regarding long-term effects and morphologic changes in the airways in order to determine the ideal role for BT in asthma. The recommended advice is undergoing BT in the context of a clinical trial or registry.

The Global Initiative for Asthma (GINA) 2023 indicates BT is a potential treatment in Step 5 of their treatment algorithm. Caution is advised in patient selection for bronchial thermoplasty. BT is associated with an increased risk of exacerbation during the three-month treatment period, and a subsequent decrease in exacerbations, but no beneficial effect on lung function or asthma symptoms compared with sham controlled patients. While extended followup of some treated patients showed a sustained reduction in exacerbations compared with pre-treatment, the recommendation is long term followup with larger cohorts comparing effectiveness and safety of the procedure are needed. The GINA report advises BT be performed in adults with severe asthma only in the context of an Independent Institutional Review Board-approved systematic registry or clinical study, so that further evidence on the effectiveness and safety of the procedure can be collected.

A 2016 Hayes, Inc. report updated in 2020 provided a Hayes rating of C for bronchial thermoplasty for severe, persistent asthma in adult patients (18 years or older) whose asthma has not been well controlled by long-acting bronchodilators and glucocorticoids. A rating of D2 is given for the treatment of mild-to-moderate asthma in adults. A D2 rating is given for all pediatric patients. These ratings are based on an overall low quality, small body of evidence.

A Cochrane Systematic Review (2014) of randomized controlled trials evaluating outcomes of interest including quality of life, asthma exacerbations, and adverse events. The authors conclude that BT provides a modest clinical benefit and quality of life and lower rates of asthma exacerbations but no significant difference in asthma control scores. The findings for the quality of life outcome were considered bias because the main benefits were seen in two studies that did not include a sham treatment group. The recommendation for clinical practice was to collect data from patients systematically in clinical registries. It was noted that further research will provide a better understanding of the mechanisms of action of bronchial thermoplasty, as well as its effect in different asthma phenotypes or in patients with worse lung function.

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code (s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provisions in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

	CPT® CODES ARE FOR INFORMATIONAL PURPOSES
CPT® CODES	**DESCRIPTION**
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

	ICD-10®CODES ARE FOR INFORMATIONAL PURPOSES
ICD10® CODES	**DESCRIPTION**
J45.20 J45.998	Asthma

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Effective Dates: 10/22/2003, 10/22/2004, 10/21/2005, 05/30/2006, 10/13/2006, 03/03/2008, 03/02/2009, 06/04/2010, 08/23/2011, 03/07/2014, 12/05/2014, 12/02/2016, 12/01/2017, 11/21/2017, 02/03/2020, 11/01/2021, 02/01/2023, 11/1/2023