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MEDICAL POLICY – 7.01.128

Bronchial Valves

BCBSA Ref. Policy:	7.01.128	
Effective Date:	Sept. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Aug. 12, 2024	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

In the chest, the lung sits in an airless sack called the pleural cavity or pleural space. The only air in the chest should be found within the lung itself. If the lung leaks air, the air can escape from the lung into the pleural space. If air leaks into the pleural space, the lung may be unable to adequately inflate, resulting in a collapsed lung or shallow, slow, or inadequate breathing. As a result, too little oxygen may get into the blood. Air leaks can occur because of disease, surgery, or injury. A type of one-way valve has been proposed as a way to try to keep air from leaking out of the lung. The umbrella-shaped device is placed in the airway and is intended to keep air from moving toward the air leak. This type of device is investigational (unproven). More studies are needed to see how well it works compared to standard treatments and to look at its overall safety.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Bronchial valves	**Bronchial valves are considered investigational in all situations including but not limited to:** • Treatment of prolonged air leaks • Treatment for individuals with chronic obstructive pulmonary disease or emphysema

Coding

Code	Description
CPT	
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure[s])

Related Information

N/A

Evidence Review

Description

Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. They have been investigated for use in individuals who have prolonged bronchopleural air leaks and in individuals with lobar hyperinflation from severe or advanced emphysema.

Background

Pulmonary Air Leaks

Proper lung functioning depends on the separation between the air-containing parts of the lung and the small vacuum-containing space around the lung called the pleural space. When air leaks into the pleural space the lung is unable to inflate, resulting in hypoventilation and hypoxemia; this condition is known as a pneumothorax. A pneumothorax can result from trauma, high airway pressures induced during mechanical ventilation, lung surgery, and rupture of lung blebs or bullae, which may be congenital or the result of chronic obstructive pulmonary disease (COPD).

Treatment

Although an air leak from the lung into the pleural space may seal spontaneously, it often requires intervention. The following practices are currently being used to try to close air leaks including the following:

- Inserting a chest tube (tube thoracostomy) and using a water seal or one-way valve to evacuate air collected in the pleural space and prevent it from reaccumulating;
- Lowering airway pressures by adjusting the mechanical ventilator;
- Using autologous blood patches; and
- Performing a thoracotomy with mechanical or chemical pleurodesis.

A bronchial valve is a device that permits one-way air movement. During inhalation the valve is closed, preventing air flow to the diseased area of the lung. The valve opens during exhalation to allow air to escape from the diseased area of the lung. When used to treat persistent air leak from the lung into the pleural space, the bronchial valve theoretically permits less air flow across

the diseased portion of the lung during inhalation, aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy. Placement of bronchial valves requires an inpatient surgical procedure. Bronchial valves can be utilized for up to 6 weeks to effect resolution of a persistent pulmonary leak.

Emphysema

Emphysema, a form of COPD, is a progressive, debilitating disease characterized by irreversible destruction of alveolar tissue. This destruction results in reduced elastic recoil, progressive hyperinflation and gas trapping with individuals experiencing chronic dyspnea, limited exercise tolerance and poor health related quality of life. In emphysematous COPD, diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. The patterns and degree of emphysema heterogeneity (i.e., the extent and distribution of air space enlargements) can be measured using computed tomography (CT) density as an indicator for tissue destruction. The most diseased portions of lung can then potentially be targeted for lung volume reduction procedures. In homogeneous emphysema, there is minor or no regional difference in disease within or between lobes of the lung.

In the US, prevalence of COPD varies widely by state, with the estimated prevalence in 2019 ranging from <4.5% in California, Colorado, Hawaii, Massachusetts, Minnesota, and Utah to >9% in Alabama, Arkansas, Kentucky, and West Virginia.[1] In 2018, chronic lower respiratory disease, primarily COPD, was the fourth leading cause of death in the US.[2] COPD mortality has decreased among Americans overall but this decline has not been observed in all sociodemographic groups. An analysis of COPD mortality between 2004 and 2018 found that African American women were the only sociodemographic group to have had an increase in COPD mortality, with an annual percent change (APC) of 1.3% (95% confidence interval [CI], 0.9% to 1.6%), compared to a decrease in men (APC -1.2%; 95% CI -1.5% to -0.9%), and no change for women overall.[3]

The Global Initiative for Chronic Obstructive Lung Disease, or GOLD, system is commonly used to categorize individuals with emphysema according to severity.[4] Stages of airflow limitation are based on the forced expiratory volume in 1 second (FEV1), or the amount of air a person can force out in 1 second after taking a deep breath. Individuals with an FEV1 of less than 50% of their predicted value are considered to have severe airflow limitation. Individuals are also grouped in the GOLD system according to categories of risk of having an exacerbation. These groups are based on number and type of exacerbations per year and self-reported symptoms such as breathlessness.

Table 1. Classification of Disease Severity

Stages of Airflow Limitation	Severity Grouping
GOLD 1 (mild): FEV1≥ 80% predicted	Group A: low risk 0-1 exacerbation per year, not requiring hospitalization, fewer symptoms
GOLD 2 (moderate): 50% ≤FEV1 <80% predicted	Group B: low risk 0-1 exacerbation per year, not requiring hospitalization, more symptoms
GOLD 3 (severe): 30% ≤FEV1 <50% predicted	Group C: high risk ≥2 exacerbations per year, or one or more requiring hospitalization, fewer symptoms
GOLD 4 (very severe): FEV1 <30% predicted	Group D: high risk ≥2 exacerbations per year, or one or more requiring hospitalization, more symptoms

FEV1: forced expiratory volume in 1 second; GOLD: Global Initiative for Chronic Obstructive Lung Disease.

Bronchial Valves

Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. During inhalation, the valve is closed, preventing air flow into the diseased area of the lung. The valve opens during exhalation to allow air to escape from the diseased area of the lung. They have been investigated for use in individuals who have prolonged bronchopleural air leaks and in individuals with lobar hyperinflation from severe or advanced emphysema.

When used to treat persistent air leaks from the lung into the pleural space, the bronchial valve theoretically permits less air flow across the diseased portion of the lung during inhalation, aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy.

The use of bronchial valves to treat emphysema is based on the improvement observed in individuals who have undergone lung volume reduction surgery (LVRS). LVRS involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for individuals undergoing lung volume reduction has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of the diseased lung. Currently, and at the time the clinical

trials were designed, very few lung volume reduction procedures were performed. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Medical management remains the most common treatment for a majority of individuals with severe emphysema.

In early trials of bronchial valves for treatment of emphysema, absence of collateral ventilation (pathways that bypass the normal bronchial airways) was associated with better outcomes, presumably because individuals with collateral ventilation did not develop lobar atelectasis (collapse). In subsequent trials, individuals were selected for absence of collateral ventilation, and it is current practice for individuals to be assessed for the presence of collateral ventilation prior to undergoing the procedure. Collateral ventilation is measured by the Chartis System, which requires bronchoscopy, or as a surrogate, CT scanning to assess the completeness of fissures. After 45 days post-procedure, residual volume can provide information on whether lung volume reduction has been achieved successfully.

Summary of Evidence

For individuals who have pulmonary air leaks who receive bronchial valves, the evidence includes the case series and a prospective cohort observational study related to the Humanitarian Device Exemption for the Spiration IBV Valve device. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. Other reports are small series of heterogeneous individuals. There is no comparative data with alternatives. This evidence is inadequate to determine the impact of this technology on the net health outcome. Thus, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe or advanced emphysema with little or no collateral ventilation between target and ipsilateral lobe who receive bronchial valves, the evidence includes multiple randomized controlled trials (RCTs) comparing bronchial valves to usual care at 6 or 12 months, one RCT comparing bronchial valves to lung volume reduction surgery (LVRS) through 12 months, systematic reviews, and a single center prospective cohort study with patient-reported outcomes. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCTs provide evidence of clinically meaningful benefit for bronchial valves compared to standard medical management on measures of lung function, exercise tolerance, and quality of life. However, confidence in these results is low due to study limitations including a lack of blinding and wide confidence intervals around estimates of effect. Across studies, there was an increased risk of serious procedure-related adverse events compared to usual care, including pneumothorax occurring in up to 27% of individuals. Results

at 24 months have been published from one RCT (EMPROVE), with evaluable data from 114 of 172 participants (66.3%). Between the 12-month visit and 24-month visit, 10 participants died (8 intervention and 2 control). Change from baseline in FEV1 remained significantly improved in the treatment group compared to control group through 24 months, but the FEV1 responder rate (15% or greater improvement from baseline) at 24 months did not differ between groups (19.7% treatment vs 13.3% control; P =.57). Acute exacerbations of COPD at the 24-month follow-up occurred in 13.7% (14 of 102) and 15.6% (7 of 45) of individuals in the treatment and control groups, respectively (P =.80). Significant improvements were maintained through 24 months on some, but not all, measures of quality of life. A RCT (CELEB) that compared bronchial valves to LVRS in 80 individuals found no statistically significant difference between treatment groups on the primary outcome (change from baseline to 12 months on the iBODE instrument, -0.27 (-0.62 to 1.17; P =.54). Notably, the magnitude of change from baseline for both groups on the i-BODE was below the 1.5-point difference considered by the study investigators to be sufficiently clinically important. The trial was limited by lack of participant blinding, high loss to follow-up, choice of a composite primary outcome, and evidence of selective outcome reporting. More participants in the bronchial valve group required additional procedures post-intervention, including 4 (8.5%) who went on to LVRS. In a prospective cohort study of patient-reported outcomes 1 year following treatment, 74.8% were satisfied with the treatment, 52.6% were satisfied with the reduction in their symptoms after treatment, and 91.4% said they would recommend the treatment to others. Confidence in these findings is limited by the study's uncontrolled design and high loss to follow-up (29.9%). The potential benefits of the procedure do not outweigh the demonstrated harms. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 2.**

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01796392[a]	Lung Function Improvement After Bronchoscopic Lung Volume Reduction With Pulmonx Endobronchial Valves Used in Treatment of Emphysema (LIBERATE)	190	Apr 2024 (post approval study, (5 year extension)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04186546[a]	Zephyr Valve Registry (ZEVR)	150	Dec 2026
NCT04302272[a]	The Spiration Valve System (SVS) Post-Market Registry Study for Severe Emphysema	150	Apr 2028

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

The 2023 GOLD publication makes the following statements on lung volume reduction interventions:[4]

- "In selected patients with heterogeneous or homogeneous emphysema and significant hyperinflation refractory to optimized medical care, surgical or bronchoscopic modes of lung volume reduction (e.g., endobronchial one-way valves, lung coils, or thermal ablation) may be considered."
- "In select patients with advanced emphysema refractory to optimized medical care, surgical or bronchoscopic interventional treatments may be beneficial."

National Institute for Health and Care Excellence (NICE)

In December 2017, NICE issued the following recommendations on endobronchial valve insertion to reduce lung volume in emphysema:[29]

1.1 Current evidence on the safety and efficacy of endobronchial valve insertion to reduce lung volume in emphysema is adequate in quantity and quality to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a multidisciplinary team experienced in managing emphysema, which should typically include a chest physician, a radiologist, a thoracic surgeon, and a respiratory nurse.

1.3 Patients selected for treatment should have had pulmonary rehabilitation.

1.4 The procedure should only be done to occlude volumes of the lung where there is no collateral ventilation, by clinicians with specific training in doing the procedure.

NICE guidance on the diagnosis and management of COPD (2018, updated 2019) included the following recommendations on lung volume reduction procedures:[18.]

Offer a respiratory review to assess whether a lung volume reduction procedure is a possibility for people with COPD when they complete pulmonary rehabilitation and at other subsequent reviews, if all of the following apply:

- They have severe COPD, with FEV1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment
- They do not smoke
- They can complete a 6-minute walk distance of at least 140 m (if limited by breathlessness).

At the respiratory review, refer the person with COPD to a lung volume reduction multidisciplinary team to assess whether lung volume reduction surgery or endobronchial valves are suitable if they have:

- Hyperinflation, assessed by lung function testing with body plethysmography and
- Emphysema on unenhanced CT chest scan and
- Optimized treatment for other comorbidities.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In October 2008, the Spiration IBV System (Spiration) was approved by the US Food and Drug Administration (FDA) through the humanitarian device exemption (H060002) process for use in controlling prolonged air leaks of the lung or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery. An air leak present on postoperative day seven is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: (1) continuous, (2) present during the normal inhalation phase of inspiration, or (3) present on normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Use of the Intrabronchial Valve System is limited to 6 weeks per prolonged air leak. FDA product code: OAZ.

Two bronchial valve systems are FDA approved for treatment of individuals with severe emphysema. In June 2018, FDA granted the Zephyr Valve system breakthrough device status with expedited approval for the bronchoscopic treatment of adult individuals with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. In December 2018, FDA approved the Spiration Valve System for adult individuals with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation. FDA product code: NJK.

Table 3. Bronchial Valve Systems Approved by FDA

Device	Indication	Manufacturer	Location	Date Approved	HDE/PMA No.
IBV Valve System	To control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS).	Spiration, Inc	Redmond, WA	10/24/08	H060002
Spiration Valve System	For adult patients with shortness of breath and	Spiration, Inc	Redmond, WA	12/03/18	P180007

Device	Indication	Manufacturer	Location	Date Approved	HDE/PMA No.
	hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation				
Zephyr Endobronchial Valve System	For the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation	Pulmonx Corporation	Redwood City, CA	06/29/18	P180002

FDA: Food and Drug Administration, HDE: human device exemption; PMA: premarket approval application.

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History

Date	Comments
01/11/11	Add to Surgery Section - New policy created with literature search through October 2010; considered investigational.
04/25/12	Replace policy. Policy updated with clinical input and a literature search through December 2011. References 10, 12 and 13 added; other references reordered. Policy statements unchanged.
01/10/13	Coding update. CPT codes 0250T – 0252T deleted as of 12/31/12; these are replaced by 31647 – 31649, which are added to the policy, along with 31651, 31660 – 31661, all effective 1/1/13.
04/16/13	Replace policy. Policy updated with a literature search through January 16, 2013. Reference 6 added; other references reordered. Policy statements unchanged. Codes 31660 and 31661 removed; they have been added to another policy and do not apply to this policy.
05/05/14	Annual Review. Policy updated with a literature search through January 7, 2014. References 2 and 8 added; other references reordered or removed. Policy statements unchanged.
05/27/15	Annual Review. Policy updated with a literature review through February 4, 2015. References 8-9 added. Policy statement edited for clarification only. ICD-10-PCS codes added per remediation.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review through April 27, 2016; reference 8 added. Policy statement unchanged.
08/01/17	Annual Review, approved July 25, 2017. Policy moved to new format. Policy updated with literature review through April 25, 2017; reference 4 added. "Endobronchial" changed to "Bronchial" in policy and title. Policy statement otherwise unchanged.
09/01/18	Annual Review, approved August 23, 2018. Policy updated with literature review through April 2018; no references added. Policy statement unchanged.
09/01/19	Annual Review, approved Aug. 6, 2019. Policy updated with literature review through April 2019; references added. Regulatory status section updated with indications for patients with severe emphysema. Policy statement unchanged.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through May, 2020; references added. Policy statement unchanged.

Date	Comments
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through May 13, 2021; references added. Updated Table 12 with corrected data from published erratum in previously included meta-analysis. Policy statements unchanged.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through April 15, 2022; references added. Policy statements revised to change terminology from "patients" to "individuals"; intent unchanged.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through April 20, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/01/24	Annual Review, approved August 12, 2024. Policy updated with literature review through April 26, 2024; reference added. Removed outdated clinical input. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.