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Bronchial Valves

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of a U.S. Food and Drug Administration (FDA) approved bronchial valve (e.g., Zephyr® Endobronchial Valve System or Spiration® Valve System) **may be considered medically necessary** for the treatment of emphysema when **ALL** of the following criteria are met:

- Confirmed diagnosis of emphysema; AND
- Age ≥ 40 years; AND
- Stable with ≤20 mg prednisone (or equivalent) daily; AND
- Forced expiratory volume (FEV_1) between 15% and 45% of predicted value at initial evaluation; AND
- 6-minute walking distance (6MWD) ≥100 m and <500 m; AND
- Non-smoking for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure.

The use of a U.S. Food and Drug Administration (FDA) approved bronchial valve (Zephyr® Endobronchial Valve System or Spiration® Valve System) **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to the following:

- Treatment of air leaks;
- Patients who have had a prior lung transplant, lung volume reduction surgery (LVRS), median sternotomy or lobectomy;
- Patients with congestive heart failure, left ventricular ejection fraction <45%, unstable cardiac arrhythmia, myocardial infarction or stroke;
- Patients with severe hypercapnia ($PaCO_2$ >50mm Hg on room air) and/or severe hypoxemia (PaO_2 <45mm Hg on room air);
- Patients with known allergies to nitinol, nickel, titanium or silicone;
- Patients with large bullae >30% of either lung;
- Patients with contraindications for bronchoscopic procedures;
- Two or more chronic obstructive pulmonary disease (COPD) exacerbations or two or more episodes of pneumonia within last 90 days;
- Evidence of active pulmonary infection;
- Unable to safely discontinue anticoagulants or platelet activity inhibitors for 7 days;
- Uncontrolled pulmonary hypertension (systolic pulmonary arterial pressure greater than 45 mm HG) or evidence or history of cor pulmonale as determined by recent echocardiogram (completed within last 90 days)
- High resolution computed tomography (HRCT) obtained within the last 90 days demonstrates:
    - Parenchymal destruction score of greater than 75% in all three right lobes or both left lobes; or
    - Emphysema heterogeneity score less than 10%; or
    - Large bullae encompassing greater than 30% of either lung.
- Resting bradycardia (less than 50 beats/min), frequent multifocal premature ventricular contractions (PVCs), complex ventricular arrhythmia, sustained supraventricular tachycardia (SVT);
- Post-bronchodilator FEV1 less than 15% or greater than 45% of predicted value at initial evaluation;
- Total lung capacity (TLC) less than 100% predicted (determined by body plethysmography) at initial evaluation;
- Residual volume (RV) less than 175% predicted (determined by body plethysmography) at initial evaluation;
- Diffusion capacity for carbon monoxide (DLCO) less than 20% predicted value at initial evaluation;
- 6MWD less than 100 meters or greater than 450 meters at initial evaluation;
- Presence of alpha-1 anti-trypsin deficiency;
- Plasma cotinine level greater than 13.7 ng/ml (or arterial carboxyhemoglobin >2.5% if using nicotine products) at initial evaluation.

Policy Guidelines

Because assessments may be performed immediately prior to the placement of valves, final coverage determination may be based on verification of little to no collateral ventilation as determined using the Chartis (Zephyr) or SeleCT (Spiration) systems.

Description

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 a result of chronic obstructive pulmonary disease (COPD).

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 patients 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 hyperinflation, 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 United States, prevalence of COPD varies widely by state, with the estimated prevalence in 2021 ranging from <4.5% in California, the District of Columbia, Hawaii, and Utah to >9% in Kentucky, Mississippi, Tennessee, and West Virginia. (6) In 2018, chronic lower respiratory disease, primarily COPD, was the fourth leading cause of death in the United States. (7) 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. (8)

The Global Initiative for Chronic Obstructive Lung Disease, or GOLD, system is commonly used to categorize patients with emphysema according to severity. (3) 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. Patients with an FEV1 of less than 50% of their predicted value are considered to have severe airflow limitation. Patients 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. Of note, group E was previously divided into 2 separate groups but was merged in 2023 to highlight the clinical significance of exacerbations.

Table 1. Classification of Disease Severity

Stages of Airflow Limitation	Severity Grouping
• GOLD 1 (mild): FEV1 ≥80% predicted • GOLD 2 (moderate): 50% ≤ FEV1 <80% predicted • GOLD 3 (severe): 30% ≤ FEV1 <50% predicted • GOLD 4 (very severe): FEV1 <30% predicted	**Group A:** 0 to 1 exacerbations per year, not requiring hospitalization, fewer symptoms **Group B:** 0 to 1 exacerbations per year, not requiring hospitalization, more symptoms **Group E:** ≥2 exacerbations per year, or one or more requiring hospitalizations,

FEV1: forced expiratory volume; 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 patients who have prolonged bronchopleural air leaks and in patients 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 patients who have undergone lung volume reduction surgery. Lung volume reduction surgery involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for patients 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 patients 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 patients with collateral ventilation did not develop lobar atelectasis (collapse). In subsequent trials, patients were selected for absence of collateral ventilation, and it is current practice for patients 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.

Regulatory Status

In October 2008, the Spiration® IBV Valve System (Spiration) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (H060002) process (9) 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 7 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 patients with severe emphysema. In June 2018, FDA granted the Zephyr Valve system (1) breakthrough device status with expedited approval 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. In December 2018, FDA approved the Spiration Valve System (2) for adult patients 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 2. Bronchial Valve Systems Approved by the 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	Spiration, Inc.	Redmond, WA	10/24/08	H060002

Spiration® Valve System	For adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation	Spiration, Inc.	Redmond, WA	12/03/18	P180007
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.

Rationale

This policy is based on a review of Food and Drug Administration documents and relevant specialty society guidelines. (1-5)

Practice Guidelines and Position Statements

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

The 2025 GOLD publication makes the following recommendations and statements on lung volume reduction interventions (see Figure 3.27 in the GOLD publication): (3)

- "In select patients with advanced emphysema, bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, health status, and lung function at 6 to 12 months following treatment. Endobronchial valves (Evidence A); lung coils (Evidence B); vapor ablations (Evidence B)."
- "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 Care and Excellence (NICE)

In December 2017, NICE issued the following recommendations on endobronchial valve insertion to reduce lung volume in emphysema: (4)

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: (5)

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
- Optimised treatment for other comorbidities.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	31647, 31648, 31649, 31651
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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8. Zarrabian B, Mirsaeidi M. A Trend Analysis of Chronic Obstructive Pulmonary Disease Mortality in the United States by Race and Sex. Ann Am Thorac Soc. Jul 2021; 18(7):1138-1146. PMID 33347376
9. U.S. Food & Drug Administration. Spiration IBV Valve System Approval Letter. October 24, 2008. Available at: <https://www.accessdata.fda.gov> (accessed December 4, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	Document updated. Coverage unchanged. Moved NOTE 1 to Policy Guidelines. No new references added; others updated/removed.
12/15/2024	Reviewed. No changes.
02/01/2024	Document updated with literature review. Coverage unchanged. References 1-3, 8, 21, 22, 27 added; other revised.
4/15/2022	Document updated. The following change was made to the Coverage: Little to no collateral ventilation as determined using the Chartis (Zephyr) or SeleCT (Spiration) systems was removed from the medically necessary statement criteria and added as NOTE 1. No new references added.
1/1/2022	Reviewed. No changes.
11/1/2020	Document updated with literature review. Coverage revised to consider the use of a U.S. Food and Drug Administration (FDA) approved bronchial valve (Zephyr® Endobronchial Valve System or Spiration® Valve System) may be considered medically necessary for the treatment of emphysema when ALL of the following criteria are met: confirmed diagnosis of emphysema; AND age 40 to 75 years; AND body mass index (BMI) less than 35kg/m2 ; AND stable with ≤20mg prednisone (or equivalent) daily; AND FEV1 between 15% and 45% of predicted value at initial evaluation; AND 6 minute walking distance (6MWD) ≥100m and <500m; AND non-smoking for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure; AND little to no collateral ventilation as determined using the Chartis (Zephyr) or SeleCT (Spiration) systems. The use of a U.S. Food and Drug Administration (FDA) approved bronchial valve (Zephyr® Endobronchial Valve System or Spiration® Valve System) is considered experimental, investigational and/or unproven for all other indications (see list of exclusions in coverage). References revised; new references 1, 7, 16, and 19 added.
2/15/2020	Document updated with literature review. Coverage unchanged but clarified to indicate endobronchial valves changed to bronchial valves. Title changed from Endobronchial Valves. References revised; new references 1-3, 8-13, 18, and 20 added.
10/15/2017	Document updated with literature review. Coverage unchanged.
10/1/2016	Reviewed. No changes.
2/1/2015	Document updated with literature review. Coverage unchanged; however all other sections were completely revised and updated.
1/1/2011	New medical document. Endobronchial valves are considered experimental, investigational and unproven for all indications, including but not limited to treatment of patients with prolonged air leaks, COPD or emphysema.