

EFFECTIVE DATE: 02|01|2026

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OVERVIEW

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.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Endobronchial valves (Zephyr Valve System™) may be considered medically necessary for the treatment of severe emphysema and hyperinflation as an alternative to lung volume reduction surgery:

- Patient has not responded to adequate medical therapy including pulmonary rehabilitation, oxygen supplementation, and optimal medication management, **AND**
- Forced expiratory volume in one second (FEV1) between 15%-45%, **AND**
- 6-minute walk distance (MWD) is >100 and <500m, **AND**
- Age 40-75 years, **AND**
- Patient has little to no collateral ventilation (as determined using the Chartis System and Quantitative lung CT analysis), **AND**
- The individual has abstained from cigarette smoking for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure, **AND**
- Does not have any of the following:
 - History of bronchiectasis, **AND**
 - Current or history of liver disease, **AND**
 - Prior lung transplant, lung volume reduction surgery, bullectomy or lobectomy, **AND**
 - Heart attack or decompensated congestive heart failure within the last 6 months, **AND**
 - Unstable/uncontrolled ischemic heart disease or unstable/ uncontrolled heart arrhythmia, **AND**
 - Allergy to nickel, titanium, or silicone, **AND**
 - Active pulmonary infection, **AND**
 - Large bullae encompassing greater than 30% of either lung, **AND**
 - Severe hypoxemia or hypercapnia or respiratory failure. For example:
 - Severe hypoxemia: PaO₂ <45 mmHg (6 kPa) on room air
 - Severe hypercapnia: PaCO₂ >60 mmHg (8 kPa) on room air

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products for bronchial valves via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Endobronchial valves (Zephyr Valve System™) may be considered medically necessary when the medical criteria above are met.

Medicare Advantage Plans

Bronchial valves are not covered in all other scenarios, including for the treatment of prolonged air leaks, as there is insufficient evidence to determine that the effects of the technology results in an improvement in the net health outcome.

Commercial Products

Bronchial valves are not medically necessary in all other scenarios, including for the treatment of prolonged air leaks, as there is insufficient evidence to determine that the effects of the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery and not medically necessary/not covered benefits/coverage.

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 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 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 United States, 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. In 2018, chronic lower respiratory disease, primarily COPD, was the fourth leading cause of death in the United States. 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.

The Global Initiative for Chronic Obstructive Lung Disease, or GOLD, system is commonly used to categorize patients with emphysema according to severity. Stages of airflow limitation are based on the 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.

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 1 or more requiring hospitalization, fewer symptoms
GOLD 4 (very severe): FEV1 <30% predicted	Group D: high risk ≥2 exacerbations per year, or 1 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 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.

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 patients. There are no comparative data with alternatives. This evidence is inadequate to determine the impact of this technology on the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

In June of 2018, the FDA approved Zephyr Endobronchial Valve system for the treatment of severe emphysema with hyperinflation. For individuals who have severe or advanced emphysema who receive

bronchial valves, the evidence includes 3 Pivotal RCTs, several meta-analyses, and systematic reviews. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. In patients with severe emphysema and low collateral ventilation, 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. Current standard medical management includes maximum pulmonary rehabilitation, medication management and surgical procedures such as lung transplantation, bullectomy and lung volume reduction surgery (LVRS). Studies evaluating LVRS in patients with severe emphysema demonstrate improvements in forced expiratory volume (FEV), exercise tolerance, and quality of life. LVRS is associated with a relatively high risk of adverse events such as pneumothorax and is not appropriate for patients who are suboptimal candidates for anesthesia.

A number of randomized controlled trials including the Liberate trial (2019), Transform trial (2017), Impact trial (2016), as well as studies published by the National Emphysema Treatment Trial research group, evaluated outcomes for over 500 patients to determine change in baseline status for lung function, exercise tolerance and quality of life for up to 12 months after endobronchial valve placement. Each study required that patients have severe emphysema with hyperinflation, have had an adequate trial of optimal medical management including maximum pulmonary rehabilitation, FEV1 between 15% and 45%, limited to no collateral ventilation (based on the Chartis assessment), and 6-minute walk distance (6MWD) of less than 450 meters. Results from the Transform study showed that 55.4% of patients treated with EBV had an increased FEV1 by 12% or more compared to 6.5% of control group. The Liberate trial determined that 44.7% of patients treated with EBV demonstrated 15% or greater improvement in FEV1 compared with 6.5% of standard of care group. Similar improvements in outcomes were reported for 6MWD and quality of life functions for the EBV groups compared to patients treated with standard of care.

A recent meta-analysis conducted by Labarca (2019) determined that Zephyr valves provided significant and clinically meaningful short-term improvements in carefully selected patients with severe emphysema and little to no collateral ventilation when compared to standard of care noting that endobronchial valves provide an important benefit for patients with high risks of comorbidities or for patients who are deemed unsuitable candidates for lung volume reduction surgery.

All of the available studies highlight the concern for adverse events including the risk for pneumothorax and infection or need for removal of the valves. For patients with severe disease, current standards of care are lung transplantation, lung volume reduction surgery, bullectomy, or lobectomy, all of which have demonstrated similar or worse risks of surgical or post-surgical complications including pneumothorax and infection. While lung volume reduction surgery is considered the gold standard for treating severe disease, the procedure involves removing portions of diseased lung which has proven to be irreversible and, in some cases, leads to further complications and negative outcomes.

Newer studies are available assessing the risk of pneumothorax in endobronchial valve placement and outline standard of care management options to reduce risk of adverse events and improve outcomes. These studies recommend a 3-day inpatient post procedure stay to monitor patients and include specific exclusion criteria for suboptimal candidates. Based on the outcomes of the randomized controlled trials and published guidelines from the American Lung Association as well as the Global Initiative for Chronic Obstructive Lung disease (GOLD), endobronchial valve placement has been identified as an effective and appropriate alternative to LVRS. Providers have been educated to submit documentation to a national multicenter registry to track outcomes and improvements in patient's lung function and quality of life. Many multicenter registries have provided clinical documentation demonstrating patient improvements. The evidence is sufficient to determine net health outcomes.

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 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.

Two bronchial valve systems are FDA approved for treatment of patients with severe emphysema. In June 2018, FDA granted the Zephyr Valve system 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 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.

CODING

The following code(s) may be considered medically necessary for Medicare Advantage Plans and Commercial Products when the medical criteria above are met:

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

RELATED POLICIES

Prior Authorization of Services, Treatments or Procedures

PUBLISHED

Provider Update, December 2025

Provider Update, August 2024

Provider Update, September 2023

Provider Update, November 2022

Provider Update, August 2021

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