EFFECTIVE DATE: 01|01|2016
POLICY LAST REVIEWED: 10|01|2025

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
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Use of bronchial valves for the treatment of prolonged air leaks or for treatment of chronic obstructive pulmonary disease (COPD) or emphysema is considered not covered due to insufficient evidence to determine that the effects of the technology results in an improvement in the net health outcomes.

Commercial Products
Use of bronchial valves for the treatment of prolonged air leaks or for treatment of chronic obstructive pulmonary disease (COPD) or emphysema is considered not medically necessary due to insufficient evidence to determine that the effects of the technology results in an improvement in the net health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable 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.

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.

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 randomized controlled trials (RCTs) comparing bronchial valves to usual care at 6 or 12 months, 1 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 patients. 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 other patients. 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.

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 codes are not covered for Medicare Advantage Plans and are not medically necessary for Commercial Products:

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

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])

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)

RELATED POLICIES

None

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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