MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Endobronchial Valves**
Policy Number	**7.01.106**
Category	**Technology Assessment**
Original Effective Date	**12/17/20**
Committee Approval Date	**12/17/20, 11/18/21, 06/16/22, 08/17/23**
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Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare, HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENTS:

I. Based upon our criteria and assessment of the peer-reviewed literature, the use of endobronchial valves (e.g., Zephyr and Spiration Valve System), has been medically proven to be effective and, therefore, is considered medically appropriate for the treatment of adults with severe emphysema when **ALL** the following criteria are met:
   A. A diagnosis of homogenous emphysema based on a difference in emphysema destruction scores between target and adjacent lobes of less than 15%;
   B. Have reduced lung function with FEV1 less than or equal to 50% predicted despite optimal medical therapy;
   C. Six-minute walk distance (6MWD) of at least 150 meters;
   D. Non-smoker greater than four-months;
   E. Little to no collateral ventilation in the target lobe;
   F. No evidence of active pulmonary infection;
   G. No evidence of large bullae encompassing greater than 30% of either lung;
   I. No allergy to nitinol (nickel-titanium) or its constituent metals (nickel or titanium); **and**
   J. No allergy to silicone (for Zephyr valve system only).

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of endobronchial valves has not been medically proven to be effective and, therefore, is considered **investigational** in **ALL** other situations, including, but not limited to:
   A. Treatment of prolonged air leaks;
   B. Treatment for patients with chronic obstructive pulmonary disease (COPD) or emphysema when interlobar collateral ventilation is present;
   C. Treatment of heterogenous emphysema.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINES:

I. Patient selection should be done by a multidisciplinary team experienced in managing emphysema after determination that patient is not a candidate for lung volume reduction surgery (LVRS).

II. Patients selected for treatment should have had pulmonary rehabilitation.

III. The procedure should be performed only by providers with specialized training using FDA-approved devices.

IV. The procedure should only be done to occlude regions of the lung where there is no collateral ventilation.

DESCRIPTION:

Endobronchial valve placement is a less-invasive option that involves implanting a 1-way valve, via bronchoscopy, to allow air flow and mucus clearance in the direction of central airways. An endobronchial valve is a synthetic device that is deployed with bronchoscopy into ventilatory airways of the lung for the purpose of controlling airflow. During inhalation, the valve is closed to prevent 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 endobronchial 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. Endobronchial valves have been investigated for use in patients who have prolonged bronchopleural air leaks and in patients with lobar hyperinflation from severe or advanced 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. Patients experience 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 a 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.

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, thus resulting in hypoventilation and hypoxemia; this condition is known as a pneumothorax. A pneumothorax can result from trauma, mechanical ventilation using high airway pressures, or lung surgery. A pneumothorax may also be caused from rupture of lung blebs or bullae, which may be congenital or a result of COPD. Bullae are permanent, air-filled spaces within the lung parenchyma that are at least 3 centimeters (cm) in size and have thin or poorly defined walls. Bullae cause the lung to ventilate poorly, thus trapping air and hyperinflating the lung, which can compress relatively normal lung tissue.

RATIONALE:

The purpose of a bronchial valve is to prevent hyperinflation of lung tissue. Bronchial valve usage to treat COPD 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. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Bronchial valves have been investigated as a non-surgical alternative to lung volume reduction surgery.

Currently, two bronchial valve systems are FDA-approved for treatment of patients with severe emphysema. In October 2008, the Spiration IBV Valve System (Olympus) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption 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 post-operative day five is considered prolonged unless present only during forced exhalation or cough. An air leak present on day five 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 six weeks per prolonged air leak. FDA product code: OAZ. In December 2018, the 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. FDA product code: NJK.

In June 2018, FDA granted the Zephyr Valve System (Pulmonx) 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.

Multiple published clinical trials have investigated the safety and efficacy of EBV therapy for individuals with severe homogenous or heterogenous emphysema, as compared to standard medical management. The IMPACT Trial by Valipour et al. (2016), the TRANSFORM Trial by Kemp et al. (2017), the LIBERATE Trial by Criner et al. (2018), and the EMPROVE Trial by Criner et al. (2019) provided clinical evidence of bronchial valve benefits, including measures of lung function, exercise tolerance, and quality of life, but also identified risks of serious adverse events, which included up to 29% of patients experiencing a pneumothorax, EBV migration or expulsion, and related infections. These clinical trials were small in size, with participation of 93 to 190 subjects, and with follow-up periods of three months to twelve months post-procedure. The EMPROVE trial evaluated effectiveness and safety of the Spiration Valve System (SVS) in patients with severe heterogenous emphysema. The authors reported significant improvement in FEV1 compared with baseline on 6-month; however, the overall responder rate was only 37%. Similarly, although the patient-centered outcomes (i.e., dyspnea and quality of life) improved in the valve group, they did so in only 53% and 54% of subjects, respectively, at 6 months.

Low et al. (2019) performed a meta-analysis of five randomized, controlled trials published between 2010 and 2016. These trials compared endobronchial valve (EBV) implantation versus standard medical treatment or sham bronchoscopy with a three to six-month follow-up time period, to investigate the efficacy and safety of bronchial lung volume reduction (BLVR) with EBV for advanced emphysema. The authors concluded that BLVR using EBV showed short-term improvement in lung function and quality of life, but with increased risk of minor hemoptysis, pneumothorax, and valve migration. Therefore, follow-up data on the studies are needed to determine the long-term efficacy of EBV therapy.

Mukhtar et al. (2019) conducted a retrospective cohort study that collected hospitalization discharge data (1,885 cases) from the Agency for Healthcare Research and Quality (AHRQ), National Inpatient Sample (NIS) in the USA for five consecutive years (2012 to 2016), to analyze mortality and financial impact of EBV insertion for the treatment of persistent air leak (PAL). The authors concluded that the study demonstrated reliable all-cause mortality of EBV, as the mortality rate remained the same throughout the study years at around 10%; however, EBV migration or expulsion, related infections, and post-deployment desaturation, in addition to its cost, are currently significant concerns related to EBV use.

In 2017, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines included, for the first time, bronchoscopic lung volume reduction (BLVR) treatment using one-way EBVs for selected patients with emphysema. The GOLD Executive Summary of 2017 identified that randomized, controlled trials of EBV placement showed statistically significant improvements in FEV1 and six-minute walk distance, compared to control therapy at six months post-intervention; however, the magnitude of the observed improvements was not clinically meaningful.

In 2020, the GOLD guidelines were updated and EBV treatment was elevated to “Evidence A,” affirming that endobronchial valves are a proven, viable, minimally invasive treatment option for severe emphysema. GOLD identified that patients with fissure integrity or lack of interlobar collateral ventilation, based on physiological assessment, may be candidates for EBV. The presence of interlobar collateral ventilation would exclude the use of endobronchial valve therapy. Additionally, patients with homogenous emphysema, who are not routinely considered candidate for LVRS, may benefit from EBV.

The 2023 GOLD updated guidelines continue to support the use of EBV as a proven, viable, minimally invasive treatment option for severe emphysema.

In December 2017, NICE (National Institute of Health and Care Excellence) issued the following recommendations on EBV insertion to reduce lung volume in emphysema:

- Current evidence on the safety and efficacy of EBV 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.
- 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.
- Patients selected for treatment should have had pulmonary rehabilitation.

- 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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	each additional lobe (List separately in addition to code for primary procedure)
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
31649	each additional lobe (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
No specific codes	

ICD 10 Codes

Code	Description
J43.0-J43.9	Emphysema (code range)
J44.0-J44.9	Chronic obstructive pulmonary disease (code range)

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* Key Article

KEY WORDS

Endobronchial valve, Zephyr Valve System, Spiration Valve System, Spiration IBV Valve System, lung volume reduction surgery

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, Endobronchial Valves are not addressed in National or Regional Medicare coverage determinations or policies.