MEDICAL POLICY

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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**
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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 has been medically proven to be effective and, therefore, is considered **medically appropriate** for the treatment of adults with severe emphysema when **ALL** of 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 < 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 m;
   D. Non-smoker > four months;
   E. Little to no collateral ventilation in the target lobe.

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; and
   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:

A bronchial 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, 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 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 caused by thoracic surgery, chest trauma, secondary spontaneous pneumothorax (related to underlying lung disease), cavitary pulmonary infections (especially tuberculosis), lung biopsies, and as a complication of mechanical ventilation. Endobronchial valves have also been investigated as an alternative to lung volume reduction surgery, in patients with lobar hyperinflation due to severe or advanced emphysematous COPD.

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 1 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.

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 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.

RATIONALE:

The purpose of a bronchial valve is to prevent hyperinflation of bullae. Bronchial valve usage to treat chronic obstructive pulmonary disease 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. There is a 29% incident rate of patients experiencing pneumothorax.

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 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 seven 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.

Currently, 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, 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.

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), and the LIBERATE Trial by Criner et al. (2018) 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.

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. Of the total 703 participants, 433 patients randomly received bronchoscopic lung volume reduction (BLVR), and 270 patients were in the control group (245 patients received standard medical therapy (SMT), and 25 patients underwent sham procedure). The analyzed data revealed improvement in the percentage change of forced expiratory volume in one second in the EBV group, compared with the control group [weighted mean difference (WMD)=11.43; 95% confidence interval (CI), 6.05-16.80; P<0.0001], and improvement in the St. George's Respiratory Questionnaire score (WMD= -5.69; 95% CI, -8.67 to -2.70; P=0.0002). There was no difference shown in the six-minute walking test (WMD=14.12; 95% CI, -4.71 to 32.95; P=0.14). The overall complication rate of EBV was not significantly different, except for an increased rate of pneumothorax [relative risk (RR)=8.16; 95% CI, 2.21-30.11; P=0.002), any hemoptysis (RR=5.01; 95% CI, 1.12-22.49; P=0.04)] and valve migration (RR=8.64; 95% CI, 2.01-37.13; P=0.004). 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 study population mean age was 61.4 ± 13.2 years, and almost two-thirds of the patients were males (67%). Pulmonary disease was the most common comorbidity observed in 56% of patients, followed by hypertension in 37% and cancer in 25%. Of note, nearly 23% of the patients were smokers. The most common documented reason for EBV placement was post-operative pneumothorax (PTX) (27%), followed by PTX complicating empyema with fistula (20%) and spontaneous PTX (6%). The average length of hospital stay was 21.8 ± 20.5 days, the mean time for chest tube placement was 3.8 ± 5.9 days, and the mean time for EBV insertion was 10.5 ± 10.3 days. Pleurodesis was performed before and after EBV placement, and in 9% and 6%, respectively. 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 2011, the British Thoracic Society published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults. The guidelines indicated the evidence insufficient to recommend routine use of bronchial valves for treatment of emphysema.

In 2017, the Global Initiative for Chronic Obstructive Lung Disease GOLD COPD 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. Subsequently, efficacy of EBVs has been studied in patients with heterogeneous or heterogeneous and homogenous emphysema, with mixed outcomes. Additional studies are needed, to define the optimal patient population to receive EBV treatment and to define the long-term durability of improvements. GOLD also recommended combining EBV treatment with pulmonary rehabilitation, to enhance patient management and improve outcomes.

In the 2020 GOLD updated report, EBV treatment was elevated to "Evidence A," affirming that endobronchial valves, like the Zephyr Valve, are a proven, viable, minimally invasive treatment option for severe emphysema. In this updated guidance, GOLD identified that patients with fissure integrity or lack of interlobar collateral ventilation based on physiological assessment may be candidates for EBV, as well as lung coil treatment, vapor ablation therapy or lung volume reduction surgery (LVRS). The presence of interlobar collateral ventilation would exclude the use of endobronchial valve therapy, however, other bronchoscopic lung reduction approaches could be considered. Additionally, patients with homogenous emphysema, who are not routinely considered candidate for LVRS, may benefit from EBV or other method of bronchoscopic lung reduction (BLVR). The presence of interlobar collateral ventilation is an exclusion in the selection of candidates for EBV placement. Additionally, the report states the effects of BLVR, including EBV, on survival or other long-term outcomes or in comparison to LVRS are unknown.

In December 2017, NICE 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.*

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.