



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Bronchial Valves

Policy #: 458

Latest Review Date: June 2022

Category: Surgery

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **bronchial valves as a treatment of prolonged air leaks** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **bronchial valves as a treatment for patients with COPD or emphysema** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Pulmonary Air Leaks

Proper lung functioning is dependent upon a 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 a variety of processes including 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.

Table 1. Classification of Disease Severity

Stages of Airflow Limitation	Severity Grouping
GOLD 1 (mild): FEV1 \geq 80% predicted	Group A: low risk 0 to 1 exacerbation per year, not requiring hospitalization, fewer symptoms
GOLD 2 (moderate): 50% \leq FEV1 <80% predicted	Group B: low risk 0 to 1 exacerbation per year, not requiring hospitalization, more symptoms
GOLD 3 (severe): 30% \leq FEV1 <50% predicted	Group C: high risk \geq 2 exacerbations per year, or 1 or more requiring hospitalization, fewer symptoms
GOLD 4 (very severe): FEV1 <30% predicted	Group D: high risk \geq 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.

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.

KEY POINTS:

This evidence review has been updated regularly with search of the MEDLINE database. Most recently, the literature was reviewed through April 15, 2022.

Summary of Evidence

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 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 a prospective cohort study with patient-reported outcomes, randomized controlled trials (RCTs), 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. 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. In a prospective cohort study of patient-reported outcomes 1 year following treatment, 74.8% were satisfied with the treatment and 10.9% were unsatisfied, 52.6% were satisfied with the reduction in their symptoms

after treatment and 24.9% were unsatisfied, 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.

Practice Guidelines and Position Statements

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

The GOLD publication makes the following statements on lung volume reduction interventions:

- "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, bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, quality of life and lung function at 6-12 months following treatment (Evidence Level A for endobronchial valves: well-designed RCTs with consistent findings in the intended population without any important limitations).

National Institute for Health and Care Excellence (NICE)

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

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. 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.

NICE guidance on the diagnosis and management of COPD (2018) included the following recommendations on lung volume reduction procedures:

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).
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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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Emphysema, Endobronchial valve, IBV valves, Emphasys, Zephyr endobronchial valve system, bronchial valve, Spiration Valve System

APPROVED BY GOVERNING BODIES:

In October 2008, the “IBV® Valve System” (Spiration, Inc, Redmond, WA) was approved by the FDA under the Humanitarian Device Exemption 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 (LVRS). An air leak present on postoperative 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 normal inhalation phase of inspiration, or (3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. IBV Valve System use is limited to six weeks per prolonged air leak.

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, 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.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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
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)
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])

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POLICY HISTORY:

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Medical Policy Group, May 2011

Medical Policy Group, March 2012

Medical Policy Group, November 2012

Medical Policy Group, February 2013

Medical Policy Group, October 2013

Medical Policy Group, February 2014

Medical Policy Group, March 2015

Medical Policy Group, June 2016

Medical Policy Group, June 2017

Medical Policy Group, June 2018

Medical Policy Group, August 2019

Medical Policy Group, June 2020

Medical Policy Group, June 2021

Medical Policy Group, June 2022

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.