



Louisiana

Bronchial Valves

Policy # 00282

Original Effective Date: 12/15/2010

Current Effective Date: 12/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers bronchial valves in all situations including, but not limited to the following to be **investigational**.*

- Treatment of prolonged air leaks; and
- Treatment for patients with chronic obstructive pulmonary disease (COPD) or emphysema.

Background/Overview

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 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

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reduction procedures. In homogeneous emphysema, there is minor or no regional difference in disease within or between lobes of the lung.

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 severity of airflow obstruction

Stages of Airflow Limitation	Severity Grouping
<ul style="list-style-type: none"> • GOLD 1 (mild): FEV1 ≥ 80% predicted • GOLD 2 (moderate): 50% ≤ FEV1 < 80% predicted • GOLD 3 (severe): <ul style="list-style-type: none"> ○ 30% ≤ FEV1 < 50% predicted • GOLD 4 (very severe): FEV1 < 30% predicted 	<p>Group A: low risk 0-1 exacerbation per year, not requiring hospitalization, fewer symptoms</p> <p>Group B: low risk 0-1 exacerbation per year, not requiring hospitalization, more symptoms</p> <p>Group C: high risk ≥ 2 exacerbations per year, or one or more requiring hospitalization, fewer symptoms</p> <p>Group D: high risk ≥ 2 exacerbations per year, or one or more requiring hospitalization, more symptoms</p>

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

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In October 2008, the Spiration^{®†} IBV Valve System (Spiration) was approved by the U.S. 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

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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. FDA product code: OAZ.

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. FDA product code: NJK.

Table 2. Bronchial Valve Systems Approved by FDA

Device	Indication	Manufacturer	Location	Date Approved	HDE/PMA No.
IBV ^{®‡} Valve System	To control 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	Spiration, Inc	Redmond, WA	10/24/08	H060002
Spiration ^{®‡} Valve System	For adult patients with shortness of breath and hyperinflation associated with	Spiration, Inc	Redmond, WA	12/03/18	P180007

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	severe emphysema in regions of the lung that have evidence of low collateral ventilation				
Zephyr [®] † Endobronchial Valve System	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	Pulmonx Corporation	Redwood City, CA	06/29/18	P180002

FDA: Food and Drug Administration, HDE: human device exemption; PMA: premarket approval application.

Rationale/Source

Description

Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. 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.

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

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inadequate to determine the impact of this technology on the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe or advanced emphysema who receive bronchial valves, the evidence includes 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. The potential benefits of the procedure do not outweigh the demonstrated harms. The evidence is insufficient to determine that the technology improves the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2011. Input generally agreed that use of bronchial valves is investigational for treating emphysema. Regarding the use of bronchial valves for treating prolonged air leaks, reviewers acknowledged that only limited case series are available. Of the 4 reviewers, 1 supported the investigational indication, 2 supported the compassionate use of valves for treating prolonged air leaks and the fourth thought that treatment of prolonged air leaks might be reasonable but had concerns about potential complications.

Practice Guidelines and Position Statements

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

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The GOLD (2020) 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:

1.1 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.

1.2 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.

1.3 Patients selected for treatment should have had pulmonary rehabilitation.

1.4 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:

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- 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).

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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some ongoing trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02382614 ^a	Safety and Effectiveness of the Spiration Valve System (SVS) in Air Leaks (VAST)	200	Dec 2019 (suspended; interim analysis and potential modification)

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NCT01796392 ^a	Lung Function Improvement After Bronchoscopic Lung Volume Reduction With Pulmonx Endobronchial Valves Used in Treatment of Emphysema (LIBERATE)	183	Feb 2023
NCT01812447 ^a	A Prospective, Randomized, Controlled Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the Spiration [®] ‡ Valve System for the Single Lobe Treatment of Severe Emphysema (EMPROVE)	172	May 2022
NCT04186546 ^a	Zephyr Valve Registry (ZEVR)	150	Dec 2024

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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- | | |
|------------|---|
| 12/01/2010 | Medical Policy Committee review |
| 12/15/2010 | Medical Policy Implementation Committee approval. |
| 12/08/2011 | Medical Policy Committee review |
| 12/21/2011 | Medical Policy Implementation Committee approval. No change to coverage. |
| 12/06/2012 | Medical Policy Committee review |
| 12/19/2012 | Medical Policy Implementation Committee approval. No change to coverage. |
| 11/07/2013 | Medical Policy Committee review |
| 11/20/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 11/06/2014 | Medical Policy Committee review |
| 11/21/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 10/29/2015 | Medical Policy Committee review |
| 11/16/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 11/03/2016 | Medical Policy Committee review |

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11/16/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

11/02/2017 Medical Policy Committee review

11/15/2017 Medical Policy Implementation Committee approval. Title change. Coverage eligibility unchanged.

11/08/2018 Medical Policy Committee review

11/21/2018 Medical Policy Implementation Committee approval. No change to coverage.

11/07/2019 Medical Policy Committee review

11/13/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/05/2020 Medical Policy Committee review

11/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	31647, 31648, 31649, 31651
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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