Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Bronchial Valves

Description/Background

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 as an alternative to lung volume reduction surgery in patients with lobar hyperinflation from severe or advanced emphysema.

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). A bronchial valve may be used to occlude the affected airway, reducing the air flow to the pleural space and helping the lung to heal.

EMPHYSEMA

In emphysematous COPD, peripheral lung tissue may form bullae. These diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. They also may rupture, causing a pneumothorax.

The use of bronchial valves to treat COPD is based on the improvement observed in patients who have undergone lung volume reduction surgery (LVRS). LVRS 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 diseased lung. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative.

Endobronchial valves have been investigated as a non-surgical alternative to LVRS. Use of a bronchial valve is thought to prevent hyperinflation of bullae and thus provide clinical improvement.

Regulatory Status:

In October 2008, the IBV® Valve System (Spiration, Inc, Redmond, WA) was approved by the U.S. Food and Drug Administration (FDA) under the Humanitarian Device Exemption (HDE) 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 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 normal inhalation phase of inspiration, or Present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. IBV Valve System use is limited to 6 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, 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 1. Bronchial Valves 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 severe emphysema in regions of the lung that have evidence of low collateral ventilation	Spiration, Inc	Redmond, WA	12/03/18	P180007
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.

Medical Policy Statement

The insertion of endobronchial valves is established for persistent bronchopleural air leak when inclusion criteria are met.

The insertion of endobronchial valves is established in adult individuals with hyperinflation associated severe emphysema when inclusion criteria are met.

Inclusionary and Exclusionary Guidelines

This procedure should be performed at a facility with the ability to admit. Admission should be based on perceived risks and/or complications.

Criteria for Bronchopleural Air Leak (Fistula)
Bronchopleural air leak causing pneumothorax that is not improving 5 or more days after chest tube placement, when site of air leak can be identified by balloon occlusion of the distal affected bronchus.

Criteria for Emphysema
Respiratory insufficiency caused by bullous emphysema in an individual found after multidisciplinary evaluation not to be a candidate for lung volume reduction surgery, **ALL** of the following must be met:

a. **Inclusion:**
   - PFT*:
     - Post BD* FEV1* 15 – 45%
     - TLC* ≥100%
     - RV* ≥150%
   - ABG* with pCO2 <60.
   - Completed pulmonary rehabilitation program or enrollment in a pulmonary rehabilitation program of at least 6-8 sessions **OR** attestation from physician that the patient has received adequate pulmonary rehabilitation to proceed with surgery.
   - CT imaging confirming intact fissure between lobes.

b. **Exclusions:**
   - Any general contraindications to bronchoscopy and/or general anesthesia
   - Lung findings:
     - Pulmonary nodule or mass/lesion requiring evaluation and/or management.
     - Giant bullae (>1/3 hemithorax) of either lung.
     - Cardiovascular event (e.g., myocardial infarction or heart failure) in the prior 6 months.
     - Recent CVA*/stroke (3 months).

- Evidence of uncontrolled pulmonary hypertension with systolic PAP >45 mmHg on TEE.
- Patients with evidence of active pulmonary infection.
- Patients with allergies to silicone, Nitinol (nickel-titanium) or constituent metals (nickel or titanium).
- Patients who have not quit smoking.

***Acronyms**
Pulmonary Function Test (PFT); bronchodilator (BD); forced expiratory volume at 1 second (FEV1); total lung capacity (TLC); residual volume (RV); arterial blood gas (ABG); pulmonary arterial hypertension (PAH); pulmonary artery pressure (PAP); cardiovascular (CV); cerebral vascular accident (CVA); transthoracic echocardiography (TTE).

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

31647 31648 31649 31651

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

TREATMENT OF PULMONARY AIR LEAKS

Clinical Context and Therapy Purpose

The purpose of placing bronchial valves in individuals who have pulmonary air leaks is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does placement of bronchial valves improve health outcomes in patients with pulmonary air leaks?

The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest is individuals with pulmonary air leaks.

Interventions
The therapy being considered is the placement of bronchial valves. A bronchial valve is a device that permits one-way air movement. 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. When used to treat persistent air leak 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.

Comparators
The following practices are currently being used:

- Inserting a chest tube (tube thoracostomy) and employing a water seal or one-way valve to evacuate air collected in the pleural space and prevent it from reaccumulating;
- Lowering airway pressures by adjusting the mechanical ventilator;
- Using autologous blood patches; and
- Performing a thoracotomy with mechanical or chemical pleurodesis.

Outcomes
The general outcomes of interest, in addition to overall survival, are reduction in symptoms (e.g., pneumothorax) and improvements in functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Case Series
No randomized controlled trials (RCTs) or comparative observational studies were identified. Only case reports and case series data are available.

The largest case series, Travaline et al (2009), reported on 40 patients treated at 17 sites in the United States and Europe; 6 of the patients had been included in previously published case reports.[1] Zephyr (Emphasys, now Pulmonx) endobronchial valves were used. Data were abstracted retrospectively from medical records. No specific eligibility criteria were reported,

and patients did not need to demonstrate that they were refractory to other treatments. All patients in the series had prolonged pulmonary air leak (mean duration of 119 days, median of 20 days). Twenty-five patients had continuous air leaks, 14 had expiratory air leaks, and 1 was unidentified. The most common co-morbidities were cancer and COPD. Prior to the procedure, 39 of the 40 patients had at least 1 chest tube. Five patients had other treatments e.g., blood patch before valve placement. The mean number of valves placed per patient was 2.9 (standard deviation [SD]:1.9) overall. After valve placement, 19 patients (47.5%) had complete resolution of acute air leak, 18 (45%) had a reduction in air leak, 2 (5%) had no change, and data were not available for 1 patient. The mean time from valve placement to chest tube removal was 21 days, and the median time was 7.5 days (data from 2 patients were not available). Eight patients had the valves removed after the air leak ceased; in 32 patients, the clinician chose to leave the valves in place. Six patients experienced adverse effects related to valve placement including valve expectoration, moderate oxygen desaturation, initial malpositioning of a valve, pneumonia and *Staphylococcus aureus* colonization. The length of follow-up was highly variable, ranging from 5 to 1,109 days. At last follow-up, 16 patients were reported to have died; none of the deaths were attributed to the valve or the valve implantation procedure. The authors concluded that the use of endobronchial valves is an effective, nonsurgical, minimally invasive intervention for patients with prolonged pulmonary air leaks.

Firlinger et al (2013) studied 13 patients with persistent continuous air leak (i.e., having an intrathroacic chest tube for >7 days despite conservative and/or surgical therapy) in Austria.[2] Spiration valves were used in 9 patients and Zephyr valves in 4 patients. Ten (77%) of 13 patients were considered responders, defined as successful chest tube removal without need for further intervention. The Spiration IBV (intrabronchial valve) was used in 6 of 10 responders and all 3 nonresponders. The authors concluded that the implantation of one-way valves leads to a significant reduction in air leakage flow and therefore is a valuable treatment option in patients with prolonged air leakage.

Gillespie et al (2011) reported on a case series of 7 patients with pulmonary air leaks evaluated for treatment with Spiration IBV valves.[3] Target airways could not be identified in two patients, and valves were placed in 7 patients. One of the 7 had 2 procedures due to development of an additional air leak after the first one was treated and resolved. The median duration of air leaks in the 7 patients before valve placement was 4 weeks (range, 2 weeks to 5 months). Complete air leak cessation occurred in 6 of 8 procedures after a mean duration of 5.2 days. The other 2 procedures resulted in reduction of air leak. There were no operative or postoperative complications attributed to the bronchial valves. The valves were removed in 5 of the 7 patients at a mean of 37 days after placement (range, 14 to 55 days). Valves were not removed in one patient who entered hospice care and, in the patient, who underwent 2 procedures because the patient declined removal. This case series shows that removable endobronchial valves appear to be a safe and effective intervention for prolonged air leaks with no procedural or valve-related complications.

The Humanitarian Device Exemption approval of the IBV Valve required post-approval study (PAS). The study was a prospective observational study to collect safety information about the IBV Valve System for the treatment of prolonged air leak. Eligible subjects were into the study on the day of valve treatment. The subjects were monitored after treatment until discharge from the hospital (a minimum of 1 night stay after the procedure). After discharge, the subjects were seen by the investigator for assessment of air leak status as clinically indicated. Valves were to be removed after the air leak is resolved. If the air leak was not resolved, the valves

were to be removed no longer than 6 weeks after device placement and other options were to be considered. A summary of the FDA PAS is provided in Table 2.

Table 2. Summary of IBV Valve PAS

Study	Countries	Sites	Dates	Participants	SAEs	Findings Regarding Air Leak Resolution
H060002 / PAS001 Prospective Cohort Study	US	11	2009-2014	39 post IBV valve placement for prolonged air leak	2[1]	32/39 per protocol follow-up: 2/32: no response 30/32: positive response 11/30: complete resolution 19/30: improvement

PAS: post-Approval Study; SAE: serious adverse event
[1]AE: one systolic arrest secondary to hypercapnia resolved prior to IBV placement and one mucus impaction of a bronchial valve.

Section Summary: Treatment of Pulmonary Air Leaks

Data on the Spiration IBV include reports of the first patients submitted to the Food and Drug Administration for the Humanitarian Device Exemption for use for prolonged air leaks as well as the results of the post-approval study completed in 2014. Other reports are small series of heterogeneous patients. Although there are no comparative data with alternatives, The evidence shows that the use of endobronchial valves is an effective, nonsurgical, minimally invasive intervention for patients with prolonged pulmonary air leaks. The evidence is adequate to determine the impact of this technology on the net health outcome.

TREATMENT OF SEVERE AND ADVANCED EMPHYSEMA

Clinical Context and Therapy Purpose

The purpose of placing bronchial valves in individuals who have severe or advanced emphysema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does placement of bronchial valves improve health outcomes in patients with severe or advanced emphysema?

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest is individuals with severe/advanced emphysema.

Interventions

The therapy being considered is placement of bronchial valves. Bronchial valves are placed in selected regions of the bronchial airways using a flexible bronchoscope after assessment to ensure little or no collateral ventilation in the region. Valves allow air to escape while blocking airflow into the treated lobe. This is intended to result in a reduction in lung volume and hyperinflation in the targeted area. Their use to treat chronic obstructive pulmonary disease is based on the improvement observed in patients who have undergone lung volume reduction surgery.

Comparators

The following practice is currently being used: medical management and lung reduction surgery.

Alternatives for the treatment of severe emphysema include medications for relief of the symptoms, smoking cessation, pulmonary rehabilitation, long-term administration of oxygen, lung volume reduction surgery, and lung transplantation.

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 are/were performed. Medical management remains the most common treatment for a majority of these patients.

Outcomes
The general outcomes of interest, in addition to overall survival, are reduction in symptoms and improvements in functional outcomes, and quality of life.

Measures of lung function include residual volume and forced expiratory volume in the first second (FEV1). Residual volume is the volume of air that remains in the lungs after maximum forceful expiration. FEV1 is determined by the volume of air a patient can force out in one second after taking a deep breath. In clinical trials of bronchial valves, response rates have been defined as an increase in FEV1 from baseline of 15%, 12% or 10%.

The 6-minute walk test (6MWT) measures physical function. Healthy subjects can typically walk 400 to 700 meters during a 6MWT. An improvement of about 30 meters in distance walked is considered the minimally important difference.

The St. George Respiratory Questionnaire (SGRQ) is used to measure quality of life in patients with emphysema. Scores range from 0 to 100, with higher scores indicating a worse quality of life. A 4-point change (decrease) is generally considered to represent a clinically meaningful difference.

The Medical Research Council (MRC) Dyspnea Scale is a measure of perceived respiratory disability. Patients indicate the degree of breathlessness related to activities on a scale from 1 (not troubled by breathlessness except on strenuous exercise) to 5 (too breathless to leave the house, or breathless when undressing).

Improvement in lung function after use of bronchial valves as part of multimodality pulmonary care should be assessed at 6 months after insertion.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Systematic Reviews

Three recent systematic reviews with meta-analyses have assessed the use of bronchial valves for patients with severe emphysema.[4,5,6] The individual studies included in these reviews are shown in Table 3 and discussed in the RCT sections, below. The most recent and comprehensive review, conducted by van Geffen et al (2019), included 7 trials of the Zephyr valve. Characteristics and results of this SR are shown in Tables 4 and 5. None of the reviews included studies of the Spiration valve.

Authors of all of the systematic reviews came to similar conclusions: 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 out to at least 12-months, with an acceptable safety profile in patients with little or no collateral ventilation in the target lobe.

Table 3. Comparison of Studies Included in SR & M-A

Study	Van Geffen et al (2019)	NICE (2018)	Van Agteren et al (2017) Cochrane
LIBERATE, Criner et al. (2018)	•		
TRANSFORM, Kemp et al. (2017)	•	•	
IMPACT, Valipour et al. (2016)	•	•	•
BeLieVer-HiFi, Davey et al. (2015)	•	•	•
STELVO, Klooster et al. (2015)	•	•	•
VENT EU, Herth et al. (2012)	•		•
VENT US, Sciurba et al. (2010)	•	•	•

Table 4. SR & M-A Characteristics

Study	Search End Date	RCTs	Participants	N (Range)	Duration (Range)
Van Geffen et al (2019)[6]	June 2018	7	Patients with emphysema, older than 35 years, post-bronchodilator FEV1<60% of predicted, and residual volume >150% of predicted	620 (50-190)	3 months-12 months

RCT: randomized controlled trial; FEV1: forced expiratory volume in 1 second.

Table 5. SR & M-A Results

Study	Residual Volume	FEV1[1]	6-min Walk Tests[2]	SGRQ	Adverse Events (all, including mortality	Penumothorax	Overall Mortality
Van Geffen et al. (2019)[6]							

Total N	600	620	620	609	620	620	620
Mean difference (95% CI), p	MD -0.57 (-0.71 to -0.43), <0.0001	MD 21.77 (17.63 to 25.90), 0•0001	MD 49.00 (31.89 to 66.10), <0•0001	MD –9.13 (–12.37 to –5.89), <0•0001	OR 9.58 (5.56 to 16.50), <0.00001	Range 1.4% to 25% in treatment groups	OR 1.84 (0.62 to 5.42), 0.27
I^2 (p)	23% (0.26)	20% (0.29)	56% (0.05)	52% (0.06)	0% (1.00)		0% (0.88)

[1]mililiters; [2]distance in meters
FEV1: forced expiratory volume in 1 second; SGRQ: St. George Respiratory Questionnaire; CI: confidence interval.

Randomized Controlled Trial (RCT)—Zephyr Valve

Seven RCTs have evaluated the Zephyr valve in patients with severe emphysema Tables 4 and 5). Only one trial (BELIEVER) used a sham procedure as a comparator; the rest were open label and compared the Zephyr valve to usual care. The BELIEVER trial was limited in that it only had a 3-month follow-up duration. The other trials followed patients for 6 or 12 months.

The trials showed statistically and clinically significant improvements on most measures of lung function (residual volume, FEV1), symptoms (MRC dyspnea scale), and quality of life (SGRQ). An exception was no difference from baseline to 3 months in SGRQ and MRC Dyspnea scale in the sham-controlled BELIEVER trial.

As noted by the authors of the Cochrane review conducted by van Agteren et al (2017) a post hoc analysis of the two earlier trials (VENT EU 2012 and VENT US 2010) showed better response rates in participants who had intact fissures. As a result, the newer trials altered their inclusion criteria to only select participants with intact fissures, thereby lowering the chance of selecting participants who had collateral ventilation, which resulted in better functional outcomes.[4]

Table 6. Summary of Key RCT Characteristics-Zephyr Valve

Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
LIBERATE, Criner et al (2018)[7]	US and Other	24	2013-2016	Heterogeneous emphysema distribution and little to no collateral ventilation	Zephyr valve (n=128)	Standard care (n=62)
TRANSFORM, Kemp et al (2017)[8]	Europe	17	2014-2016	Heterogenous emphysema and absence of collateral ventilation	Zephyr valve (n=65)	Standard care (n=32)
IMPACT, Valipour et al (2016)[9]	Austria, Germany, Netherlands	15	2014-2016	Homogenous emphysema and absence of collateral ventilation	Zephyr valve (n=43)	Standard care (n=50)
Stelvio, Klooster et al (2015)[7]	Netherlands	1	NR	Severe emphysema and confirmed absence of collateral ventilation	Zephyr valve (n=34)	Standard care (n=34)
BELIEVER HiFi, Davey et al (2015)[10]	England	1	2012-2013	Heterogeneous emphysema and intact interlobar fissures	Zephyr valve (n=25)	Sham procedure (n=25)

VENT EUROPE, Herth et al (2012)[9]	Multiple European	23	2005-2009	Severe heterogenous emphysema	Zephyr valve (n=111, 44 with complete fissure)	Standard care (n=60, 19 with complete fissure)
VENT US, Sciurba et al (2010)[11]	US	31	2004-2006	Severe heterogenous emphysema	Zephyr valve (n=220)	Standard care (n=101)

RCT: randomized controlled trial, NCT: National Clinical Trial; NR: Not reported.

Table 7. Summary of Key RCT Results-Zephyr Valve

Study	FEV1	6-Minute Walk Distance	SGRQ	MRC Dyspnea Scale	Adverse Events	Pneumothorax	Mortality
LIBERATE (2018)	Patients with 15% or greater improvement at 12 months	Change from baseline at 12 months	Change from baseline at 12 months	Change from baseline at 12 months	Respiratory serious AEs at 45 days	At 12 months	At 12 months
Total N	190	190	190	190	190	190	190
Zephyr valve	47.7%	12.98 (81.54)	-7.55 (15.71)	-0.5 (1.17)	35.2%	34/128 (26.6)	4/128 (3.1%)
Standard care	16.8%	-26.33 (81.50)	-0.50 (15.50)	0.3 (1.03)	4.8%	0/62 (0%)	0/62 (0%)
Between-group difference (95% CI)	Difference 31.0% (18-43.9), p<0.001	39.31 (14.64 to 63.98)	-7.05 (-11.84 to -2.27)	-0.8 (-1.1 to -0.4)			
p-valve	<0.001	0.002	0.004	<0.001	<0.001	<0.05	NS
TRANSFORM (2017)	Patients with 12% or greater improvement at 6 months	Change from baseline at 6 months	Change from baseline at 6 months	Change from baseline at 6 months	Respiratory serious AEs at 6 months	At 6 months	At 6 months
Total N	97	97	97	97			
Zephyr valve	55.4%	36.2 (76.9)	-7.2 (15.1)	-0.56 (1.04)	31/65 (47.7%)	19/65 (29.2%)	1/65 (1.5%)
Standard care	6.5%	-42.5 (68.2)	-0.7 (10.4)	0.00 (0.86)	3/32 (9.4%)	0/32 (0%)	0/32 (0%)
Difference		78.7 (46.3 to 111.0)	-6.5 (-12.4 to -0.6)	-0.56 (-0.99 to -0.14)			
p-value	<0.001	<0.001	0.031	0.010	<0.001	NR	NR
IMPACT (2016)	Improvement at 3 months, L	Change from baseline at 3 months, M	Change from baseline at 3 months	Change from baseline at 3 months	Respiratory serious AEs at months		
Total N	93	90	85	91	93	93	93
Outcome (3 months)				Change from baseline			

Zephyr valve	0.10 (0.18)	22.6 (66.6)	-8.63 (11.2)	-0.39 (1.00)	26/43 (44.2%)	12/43 (25.6%)	0/43 (0%)
Standard care	-0.02 (0.10)	-17.3 (52.8)	1.01 (9.3)	0.18 (0.98)	8/50 (12.0%)	0/50 (0%)	1/50 (2%)
Difference	0.12 (0.06 to 0.18)	40.0 (15 to 65)	-9.64 (-14.09 to -5.20)	-0.57 (-0.98 to -0.16)			
p-value	<0.0001	0.002	<0.0001	0.007	<0.001	<0.001	NS
STELVIO (2015)	Improvement at 6 months, ml	Change from baseline at 6 months, meters			Serious AEs at 6 months	At 6 months	All deaths at 6 months
Total N	68	68			68	68	68
Zephyr valve	161 (80 to 142)	60 (35 to 85)			23/34	6/34 (18%)	1/34 (3%)
Standard care	21 (-9 to 52)	-14 (-25 to -3)			5/34	0/5 (0%)	0/34 (0%)
Difference	17.8 (7.6 to 28.0)	74 (47 to 100)					
p-value	0.002	<0.001			<0.001	0.02	1.00
BELIEVER HI-FI (2015)	Improvement at 3 months L, median (IQR)	Change from baseline at 3 months, median (IQR)	Change from baseline at 3 months, median (IQR)	Change from baseline at 3 months, median (IQR)			
Total N	50	50	50	50	50	50	50
Zephyr valve	0.06 (0.02 to 0.38)	25 (7 to 64)	-4.40 (-16.93 to 6.76)	0 (-1 to 0)		2/25 (8.0%)	2/25 (8.0%)
Sham	0.03 (0 to 0.06)	3 (-14 to 20)	-3.57 (-7.67 to 2.55)	0 (-1 to 0)		1/25 (4.0%)	0/25 (0%)
p-value	0.0326	0.0119	0.3454	0.4037		1.0	0.49
VENT Europe	% change at 12 months, mean (SD), patients with complete fissure only	% change at 12 months, mean (SD), patients with complete fissure only	Change at 12 months, points, patients with complete fissure only		Serious complications up to 3 months	Up to 3 months	At 12 months, patients with complete fissure only
Total N	63	63	63		171	171	63
Zephyr valve	15% (29%)	13% (35%)	0 (15)		xx	xx	2/44 (5%)
Standard Care	-2% (22%)	10% (44%)	4 (11)				1/19 (5%)
p-value	0.04	0.8	0.10				NR
VENT US	% change at 6 months	Median % change	Mean change at 6	Mean change at 6	Major AEs at 90 days	At 90 days	At 90 days

		at 6 months	months, points	months, points			
Total N	321	321	321	321	301	301	301
Zephyr valve	4.3% (1.4 to 7.2)	2.5 (-1.1 to 6.1)	-2.8 (-4.7 to -1.0)	-0.1 (-0.21 to 0.09)	9/214 (4.2%)	4.2%	2/214 (0.9%)
Standard care	-2.5% (-5.4 to 0.4)	-3.2 (-8.9 to 2.4)	0.6 (-1.8 to 3.0)	0.2 (0.01 to 0.37)	0/87 (0%)	0%	0/87 (0%)
Difference	6.8 (2.1 to 11.5)	5.8 (0.5 to 11.2)	-3.4 (-6.7 to 0.2)	-0.3 (-0.50 to -0.01)			
p-value	0.005	0.04	0.04	0.04	0.06	0.07	1.00
Summary[2]	Range						

CI: confidence interval; HR: hazard ratio; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

Randomized Controlled Trials-Spiration Valve

Two RCTs of the Spiration valve in patients with emphysema have been published.[12,13] A third trial has not been published in a peer-reviewed medical journal, but partial results have been presented as a conference poster and results were submitted to the FDA as part of the Spiration PMA application.[14]

The EMPROVE trial showed improvements in FEV1, SGRQ, and MRC Dyspnea Scale in the Spiration group compared to usual care, but no significant difference between groups in the 6MWT.[14] Serious AEs and pneumothorax were more frequent in the Spiration group. Results of the REACH trial were mostly positive but also mixed, with improvements in FEV1, 6MWT, and SGRQ, but not the MRC Dyspnea Scale. The sham-controlled IBV Valve trial showed statistically significant results favoring the Spiration valve with clinically acceptable risk-benefit profile.

Table 6. Summary of Key RCT Characteristics-Zephyr Valve

Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
EMPROVE[14]	US and Canada	31	2013-2017	Severe emphysema without interlobular collateral ventilation	Spiration valve (n=113)	Standard care (n=59)
REACH, Li et al (2018)[13]	China	12	2013-2017	Severe emphysema and intact interlobular fissures	Spiration valve (n=72)	Standard care (n=35)
IBV Valve, Wood et al (2014)[12]	US	36	2007-2017	Emphysema, airflow obstruction, hyperinflation, and severe dyspnea	Spiration valve (n=142)	Sham procedure (n=135)

RCT: randomized controlled trial; NCT: national clinical trial.

Table 7. Summary of Key RCT Results-Spiration Valve

Study	FEV1	6-Minute Walk Distance	SGRQ	MRC Dyspnea Scale	Adverse Events	Pneumothorax	Mortality
					Thoracic serious		

					AEs at 6 months		
EMPROVE[14]	15% improvement from baseline at 6 months	Change from baseline at 6 months, meters	Change from baseline at 6 months	Change from baseline at 6 months			
Total N	172				172	172	172
Spiration valve	36.8%				31%	14%	6 (5.3%)
Standard care	10.0%				11.9%	0%	1 (1.7%)
Difference (95% CI)	26.8%	6.9 (-14.2 28.2)	-13 points (-17.4 - 8.7)	-0.6 (-0.9 - 0.3)			
p-valve							
REACH[13]	Change from baseline at 6 months (liters)	Change from baseline at 6 months, meters	Change from baseline at 6 months	Change from baseline at 6 months	Total serious AEs at 6 months		
Total N	96	96	95	96	99	99	99
Spiration valve	0.091 (0.156, 0.052)	20.82 (-0.58, 42.22)	-8.39 (-12.69 - 4.08)	-0.73 (-0.96 - 0.50)	22/66 (33.3%)	5/66 (7.6%)	0/66 (0%)
Standard care	-0.24 (0.142 -0.072)	-15.58. (-40.12, 8.96)	2.11 (-3.87, 8.08)	-0.36 (-0.71 - 0.01)	8/33 (24.2%)	0%	1/33 (3.0%)
Difference							
p-value	0.001	0.042	0.007	0.091	NR	NR	99
IBV Valve[12]	Change from baseline at 6 months (liters)	Change from baseline at 6 months, meters	Change from baseline at 6 months	Change from baseline at 6 months	Total serious AEs at 6 months	At 6 months	
Total N	250	253	277	242	277	277	277
Spiration valve	-0.07 (SD 0.17)	-24.02 (SD 69.81)	2.15 (16.36)	-0.24 (1.02)	20/142 (14.1%)	3/142 (2.1%)	6/142 (4.2%)
Sham	0.00 (SD 0.16)	-3.0 (76.63)	-1.41 (11.26)	-0.14 (1.00)	5/135 (3.7%)	0/135 (0%)	1/135 (0.7%)
Difference	(-0.11 -0.02)	(-38.84 - 2.44)	(0.04, 7.07)		10.4% (4.0, 17.1)	2.1% (0.3, 5.1)	3.5% (0.2, 7.5)

CI: confidence interval; HR: hazard ratio; NNT: number needed to treat; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; SD: standard deviation

Tables 8 and 9 summarize the design and conduct limitations of the included RCTs. In all but 2 trials, a major limitation was a lack of blinding . The initial publication of the VENT study data included only the USA arm since its size was sufficient to support the a priori power calculation. The size of the European arm of the VENT study was smaller than the a priori estimate. Two trials had follow-up durations less than 6 months. None of the studies compared

bronchial valves to lung volume reduction surgery. Although used for FDA approval, results of the EMPROVE trial have not yet been fully published.

Table 8. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
LIBERATE					
TRANSFORM					
IMPACT					1,2
STELVIO					
BELIEVER HI-FI					1,2
VENT Europe	4				
VENT US					
EMPROVE					
REACH					
IBV Valve					

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
LIBERATE	3	1				
TRANSFORM		1				
IMPACT		1				
STELVIO		1				
BELIEVER HI-FI						
VENT Europe		1			3	
VENT US		1				
EMPROVE		1	2,3			
REACH		1				
IBV Valve						

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Treatment of Severe or Advanced Emphysema

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.

SUMMARY OF EVIDENCE

For individuals who have pulmonary air leaks who receive endobronchial valves, the evidence includes 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. Although there are no comparative data with alternatives, the evidence shows the use of endobronchial valves as an effective, nonsurgical, minimally invasive intervention for patients with prolonged pulmonary air leaks. The evidence is sufficient to determine the impact of this technology on the net health outcome.

For individuals who have severe or advanced emphysema who receive endobronchial valves, the evidence includes 11 randomized controlled trials (RCTs) and 3 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. Bronchial valve treatment is feasible and safe for patients with advanced heterogenous emphysema, especially those with no evidence of collateral ventilation. The evidence is sufficient to determine the effects of the technology on health outcomes.

Ongoing Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04186546[a]	Zephyr Valve Registry (ZEVR)	150	Dec 2026
NCT06332885	Zephyr valve Japan post-marketing surveillance	140	Apr 2028
NCT04517916	Zephyr Etude post-inscription (French registry)	155	Sep 2025
NCT06181357	Trial evaluating the rate of pneumothorax in severe emphysema secondary to endoscopic volume reduction with two stage Zephyr® valves vs. endoscopic volume reduction with one stage Zephyr® valves (REPEAT)	244	Jun 2027
Unpublished			
NCT02382614	Safety and Effectiveness of the Spiration Valve System (SVS) in Air Leaks (VAST)	200	Dec 2021
NCT04161235[a]	Post-Market Clinical Evaluation of the Zephyr Valve 5.5-LP EBV for Bronchoscopic Lung Volume Reduction (BLVR) Procedures	2	Jun 2021

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial.

SUPPLEMENTAL INFORMATION

Clinical Input Received through 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 through one physician specialty society and three academic medical centers while this policy was under review by BCBSA for March 2011. Those providing input generally agreed that use of endobronchial valves is investigational for the treatment of emphysema. Regarding use of endobronchial valves for treating prolonged air leaks, reviewers acknowledged that only limited case series are available. Of the four reviewers, one supported the investigational indication; two 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

British Thoracic Society (BTS)

In 2011, the BTS issued a guideline regarding advanced diagnostic and therapeutic flexible bronchoscopy in adults. It states that EBVs appear to be safe for the treatment of patients with severe emphysema (evidence level 1) and EBV insertion in patients with severe emphysema and hyperinflation promotes modest improvements in lung function (evidence level 2). Based on these evidence statements, the guideline indicates that there was currently insufficient evidence to recommend use of EBVs (note the 2011 publication date, which predates much of the published evidence reviewed in this report). However, EBVs may be considered for treatment of selected patients who have severe emphysema and hyperinflation with heterogeneous disease in the absence of significant collateral ventilation or in patients with a complete fissure by computed tomography (CT) scan (Du Rand et al., 2011). This guideline has been archived, according to the BTS website.

National Institute for Health and Care Excellence (NICE)

In 2017, NICE published recommendations on endobronchial valve insertion to reduce lung volume in emphysema. The recommendations include:[13]

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 those 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:[14]

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).

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**
- optimized treatment for other comorbidities.

Global Initiative for Chronic Obstructive Lung Disease (GOLD)
The GOLD (2024) publication makes the following statements on lung volume reduction interventions:[1]

- "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).

U.S. Preventive Services Task Force Recommendations
Not applicable.

Government Regulations
National/Local:

There is no national or local coverage determination on the use of bronchial valves for the treatment of emphysema. The IBV® Valve System has been given Humanitarian Device Exemption approval from the FDA to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy or lung volume reduction surgery. Covered when done in the context of an approved clinical trial.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Endobronchial Ultrasound (EBUS)
- Electromagnetic Navigation Bronchoscopy
- Lung Volume Reduction Surgery (retired)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/11	1/25/11	1/4/11	Joint policy established
7/1/13	4/16/13	4/22/13	New codes added to policy. Policy formatted to match BCBSA policy. No change in policy status.
1/1/15	10/24/14	11/3/14	Updated rationale and references. No change in policy status.
1/1/16	10/13/15	10/27/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine policy maintenance, updated references/rationale sections.
11/1/17	8/15/17	8/15/17	Routine policy maintenance. Updated clinical trial section. No change in policy status.
11/1/18	8/21/18	8/21/18	Routine policy maintenance. Change in policy title from “Endobronchial” to “Bronchial.” No change in policy status.
11/1/19	8/20/19		Reorganized and updated rationale section. Added NICE and GOLD guidelines. No change in policy status.
5/1/20	2/18/20		Discussed the LIBERATE study, coverage comparisons and Hayes rating. No change in policy status.
9/1/21	7/15/21		Status changed to established with criteria.
9/1/22	TABLED		Routine policy maintenance, no change in policy status. Discussion re: statement in rationale that this is an inpatient procedure. Policy tabled – 6/21/22
11/1/22	8/16/22		Two bullets under exclusions rewritten with input from Dr. Simoff for clarification purposes: • Cardiovascular event (e.g., myocardial infarction or heart failure) in the prior 6 months

			• Evidence of uncontrolled pulmonary hypertension with sPAP >45 mmHg on TEE No change in policy status.
9/1/23	6/13/23		Routine policy maintenance, RV changed from 175% to 150%. Vendor managed: N/A. (ds)
9/1/24	6/17/24		Updated exclusion section per FDA guidelines. No change in policy status. Vendor managed: N/A (ds)

Next Review Date: 2nd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BRONCHIAL VALVES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered per policy.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.