MEDICAL POLICY

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP 1.122

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**12/1/2024**

I. POLICY

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Bronchial valves that have been approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** in the treatment of adults with hyperinflation related to advanced emphysema in regions of the lung that have little to no collateral ventilation.

Bronchial valves that have been approved by the U.S Food and Drug Administration (FDA) for air leaks are considered **not medically necessary.** Please see Policy Guidelines for more information.

Any other use of bronchial valves is considered **investigational.** There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-References:

MP 2.010 Clinical Trials and Expanded Access Services

MP 2.103 Off-Label Use of Medications and Other Interventions

POLICY GUIDELINES

The IBV® Valve System has FDA approval through the Humanitarian Device Exemption process. An HDE may only be used in facilities that have Institutional Review Board (IRB) oversight.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

III. DESCRIPTION/BACKGROUND

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Emphysema

Emphysema, a form of COPD, is a progressive, debilitating disease characterized by irreversible destruction of alveolar tissue. This destruction results in reduced elastic recoil, progressive hyperinflation, and gas trapping. Patients experience chronic dyspnea, limited exercise tolerance and poor health related quality of life. In emphysematous COPD, diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflate, compressing relatively normal lung tissue. The patterns and degree of emphysema heterogeneity (i.e., the extent and distribution of air space enlargements) can be measured using computed tomography (CT) density as an indicator for tissue destruction. The most diseased portions of 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.

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≥ 80% predicted	**Group A: low risk** 0-1 exacerbation per year, not requiring hospitalization, fewer symptoms
• GOLD 2 (**moderate**): 50% ≤FEV1 <80% predicted	**Group B: low risk** 0-1 exacerbation per year, not requiring hospitalization, more symptoms
• GOLD 3 (**severe**): 30% ≤FEV1 <50% predicted	**Group C: high risk** ≥2 exacerbations per year, or one or more requiring hospitalization, fewer symptoms
• GOLD 4 (**very severe**): FEV1 <30% predicted	**Group D: high risk** ≥2 exacerbations per year, or one or more requiring hospitalization, more symptoms

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Bronchial Valves
Bronchial valves are synthetic devices inserted 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, which helps with air trapping. 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 clinical situation where a bronchial valve is likely beneficial, is as an alternative to more invasive procedures. The bronchial 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.

Societal Guidance
In December 2017, NICE (National Institute of Health and Care Excellence) 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.

Regulatory Status

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 (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 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.

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 and Manufacturer	Indication	Date Approved	HDE/PMA No.
Spiration® Valve System ***Spiration, Inc***	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	12/03/18	P180007
Zephyr® Endobronchial Valve System ***Pulmonx Corporation***	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	06/29/18	P180002
IBV® Valve System ***Spiration, Inc***	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 (LVRS)	10/24/08	H060002

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

IV. RATIONALE

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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. Travaline et. al is the largest study. In this multicenter study, 40 patients with persistent air leaks were treated with endobronchial valves. Nineteen patients (47.5%) had a complete resolution of the air leak, 18 (45%) had a reduction, 2 had no change, and 1 had no reported outcome. The mean time from valve insertion to chest tube removal was 21 days (median, 7.5 days; interquartile range [IQR], 3 to 29 days) and from valve procedure to hospital discharge was 19 ± 28 days (median, 11 days; IQR, 4 to 27 days). They concluded that use of endobronchial valves is an effective, nonsurgical, minimally invasive intervention for patients with prolonged pulmonary air leaks. The limitation of this study was no control group. Other studies have similar limitations. The Valves Against Standard Therapy study has been terminated as of March 2023. The evidence is insufficient to determine if the technology results in an improvement in net 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. For emphysema, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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AIR LEAK (AL) is a clinical phenomenon associated with the leakage or escape of air from a cavity that contains air into spaces that usually, under normal circumstances, do not have air. The terminology air leak syndrome (ALS) is the presence of air leak with associated symptoms of respiratory distress.

HUMANITARIAN USE DEVICE (HUD) is medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year

HUMANITARIAN EXEMPTION DEVICE (HDE) is a marking application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
31647	31648	31649	31651					

ICD-10-CM Diagnosis Codes	Description
J43.0	Unilateral pulmonary emphysema
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified
J93.82	Other air leak

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.122	**04/17/2020 Consensus Review.** Policy statement unchanged. Background, Rationale, and References updated. Coding reviewed.
	05/14/2021 Major Review. Bronchial Valves changed from E/I to medically necessary when criteria met. Related policy removed as it has been retired. Background, Rationale, Coding and References updated.
	07/15/2022 Minor Review. Policy updated; air leaks now listed as NMN. New policy guidelines, cross ref. Lit review, coding review with additional ICD10. Updated references.
	07/06/2023 Consensus Review. No changes to policy statement. Updates to background, rationale, references. Formatting changes to FDA reg table. Coding reviewed.
	01/18/2024 Administrative Update. Added clinical benefit.
	07/25/2024 Consensus Review. No change to policy statement. New references. Coding reviewed.

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