MEDICAL POLICY

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP-1.122

Original Issue Date (Created):	**9/1/2011**
Most Recent Review Date (Revised):	**6/7/2018**
Effective Date:	**8/1/2018**

I. POLICY

TOP

Bronchial valves are considered **investigational** in situations including, but not limited to:

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

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

Only one endobronchial valve device has approval from the U.S. Food and Drug Administration (FDA) through the Humanitarian Device Exemption (HDE) process for use in prolonged pulmonary air leaks.

Cross-reference:
MP-1.025 Lung Volume Reduction Surgery for Severe Emphysema

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.128, Endobronchial Valves. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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III. DESCRIPTION/BACKGROUND

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Endobronchial valves are synthetic devices that are deployed with bronchoscopy into ventilatory airways of the lung for the purpose of controlling airflow. They have been investigated for use in patients who have prolonged broncho-pleural air leaks, as well as an alternative to lung volume reduction surgery (LVRS) in patients with lobar hyperinflation from severe emphysema.

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).

Treatment

Although an air leak from the lung into the pleural space may seal spontaneously, it often requires intervention. Techniques currently employed to attempt air leak closure include the following:

- 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,
- Performing a thoracotomy with mechanical or chemical pleurodesis.

Abronchial valve is a device that permits one-way air movement. During inhalation the valve is closed preventing air flow to the diseased area of the lung. The valve opens during exhalation to allow air to escape from the diseased area of the lung. When used to treat persistent air leak from the lung into the pleural space, the endobronchial valve theoretically permits less air flow across the diseased portion of the lung during inhalation, aiding in air leak closure. The valve may be placed, and subsequently removed, by bronchoscopy.

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.

Treatment

Use of a bronchial valve is thought to prevent hyperinflation of bullae. Their use to treat COPD is based on the improvement observed in patients who have undergone lung volume reduction surgery. Lung volume reduction surgery involves excision of peripheral emphysematous lung tissue, generally from the upper lobes. The precise mechanism of clinical improvement for

patients undergoing lung volume reduction has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of the diseased lung. The procedure is designed to relieve dyspnea and improve functional lung capacity and quality of life; it is not curative. Bronchial valves have been investigated as a nonsurgical alternative to lung volume reduction surgery.

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. Use of the Spiration® Intrabronchial Valve for emphysema is considered off-label. FDA product code: OAZ

In December 2008, the "Zephyr Endobronchial Valve" (formerly Emphasys, now Pulmonx, Redwood City, CA) was considered by the Anesthesiology and Respiratory Therapy Device Panel for use as a permanent implant intended to improve forced air expiratory volume in 1 second (FEV1) and 6-minute walk test distance in patients with severe, heterogeneous emphysema who have received optimal medical management. The panel declined to recommend the device for FDA approval. As of May 2018, the Zephyr Endobronchial Valve has not been approved by FDA.

IV. RATIONALE

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Summary of Evidence

For individuals who have pulmonary air leaks who receive endobronchial valves, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only available data on endobronchial valves for treating persistent air leaks are uncontrolled trials with small numbers of heterogeneous patients. Data on the Spiration IBV Valve System approved by the FDA with a humanitarian device exemption are particularly limited. While these valves were successfully placed in 40 patients in a multicenter case series and other series, these case series do not provide any comparative evidence with existing alternatives. 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 seven RCTs and a systematic review of these trials. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. Of the seven RCTs, five did not use an FDA-approved valve. For the FDA-approved Spiration® IBV Valve System, there was no improvement in quality of life or exercise capacity in the combined results. Although some outcomes of the trials were statistically significant for bronchial valve treatment, the magnitude of the difference was generally of uncertain clinical significance. Moreover, the numerous adverse events experienced by patients who received bronchial valves in these trials raise concerns about treatment safety. Overall, it is not possible to determine whether there is a clinically meaningful benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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N/A

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 contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross 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. Capital BlueCross 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.

Endobronchial valves are considered investigational; therefore, not covered:

CPT Codes®								
31647	31648	31649	31651					

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IX. REFERENCES

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2. *Firlinger I, Stubenberger E, Muller MR, et al. Endoscopic one-way valve implantation in patients with prolonged air leak and the use of digital air leak monitoring. Ann Thorac Surg. Apr 2013;95(4):1243-1249. PMID 23434254*
3. *Gillespie CT, Sterman DH, Cerfolio RJ, et al. Endobronchial valve treatment for prolonged air leaks of the lung: a case series. Ann Thorac Surg. Jan 2011;91(1):270-273. PMID 21172529*
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11. *Wood DE, Nader DA, Springmeyer SC, et al. The IBV Valve trial: a multicenter, randomized, double-blind trial of endobronchial therapy for severe emphysema. J Bronchology Interv Pulmonol. Oct 2014;21(4):288-297. PMID 25321447*

12. *Du Rand IA, Barber PV, Goldring J, et al. Summary of the British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax. Nov 2011;66(11):1014-1015. PMID 22003155*
13. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.128, Bronchial Valves. June 2018.*

X. POLICY HISTORY

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MP-1.122	**CAC 4/26/11** New Policy. Adopted BCBSA. Placement of endobronchial valves is considered investigational. Endobronchial valves were previously addressed in another CBC MP, Lung Reduction Procedures (Investigational).
	CAC 6/26/12 Consensus review; no changes, references updated.
	2013 Codes added 12/20/2013
	03/28/13 Admin code changes
	CAC 9/24/13 Consensus review. References updated, but no changes to the policy statements. FEP variation revised to refer to the FEP medical policy manual. Rationale and policy guidelines added.
	CAC 7/22/14 Consensus. No change to policy statements. References updated.
	CAC 7/21/15 Consensus review. Policy statement edited for clarification only. Reference and rationale update**.** Codes reviewed.
	CAC 7/26/16 Consensus review. No change to policy statement. Regulatory Status, Rationale and Reference sections updated. Coding reviewed, removed 31634, 31660, 31661
	Administrative Update 11/23/16 Variation reformatting.
	CAC 9/26/17 Consensus review. Policy title revised to "Bronchial Valves". No changes to the policy statements. Background, rationale and references updated. Coding reviewed.
	6/7/18 Consensus. No change to policy statements. References updated. Rationale condensed.

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