

Corporate Medical Policy

Endobronchial Valves

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Origination:	11/2010
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Description of Procedure or Service

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 or advanced emphysema.

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).

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.

An endobronchial 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.

Endobronchial valves have also been investigated for use in severe emphysematous COPD. 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. Use of an endobronchial valve is thought to prevent hyperinflation of these bullae.

Consideration for the use of endobronchial valves in COPD is based on the improvement observed in patients who have undergone lung volume reduction surgery (LVRS). LVRS involves excision of

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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.

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.

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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Endobronchial valves are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Endobronchial Valves are covered

Not applicable.

When Endobronchial Valves are not covered

Endobronchial valves are considered investigational in all situations including, but not limited to:

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

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Policy Guidelines

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 or advanced emphysema.

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. 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 11 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, but there was a greater risk of serious adverse events compared to usual care. Because of limitations in study designs, especially a lack of blinding, significant heterogeneity across studies on some measures, and a higher risk of serious adverse events, with up to 29% of patients experiencing pneumothorax, the evidence is insufficient to determine that the technology improves the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 31647, 31648, 31649, 31651

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration. IBV® Valve System. Summary of safety and probable benefit. Available online: http://www.accessdata.fda.gov/cdrh_docs/pdf6/H060002b.pdf. Last accessed October 26, 2010.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 11/11/10

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U.S. Food and Drug Administration. IBV® Valve System. Summary of safety and probable benefit. Available online: http://www.accessdata.fda.gov/cdrh_docs/pdf6/H060002b.pdf. Last accessed January 2012.

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/9/12

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/14/13

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/13/14

Specialty Matched Consultant Advisory Panel review 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 3/12/15

Specialty Matched Consultant Advisory Panel review 3/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/11/15

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/16/16

Specialty Matched Consultant Advisory Panel review 3/2017

van Agteren JE, Hnin K, Grosser D, Carson KV, Smith BJ. Bronchoscopic lung volume reduction procedures for chronic obstructive pulmonary disease. [Cochrane Database Syst Rev.](#) 2017 Feb 23;2:[CD012158.] [doi: 10.1002/14651858.CD012158.pub2.] Available from: <http://www.nlm.nih.gov/citingmedicine>

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Specialty Matched Consultant Advisory Panel review 3/2019

National Institute for Health and Care Excellence. Endobronchial valve insertion to reduce lung volume in emphysema. Available at: <https://www.nice.org.uk/guidance/IPG600/chapter/1-Recommendations>. Accessed May 9, 2019

National Institute for Health and Care Excellence. Chronic obstructive pulmonary disease in over 16s: Diagnosis and management. Available at: <https://www.nice.org.uk/guidance/ng115>. Accessed May 9, 2019.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/13/19

Specialty Matched Consultant Advisory Panel review 3/2020

Policy Implementation/Update Information

12/21/10 New policy issued. Endobronchial valves are considered **investigational** as a treatment of prolonged air leaks. Endobronchial valves are considered **investigational** as a treatment for patients with COPD or emphysema. Notice given 12/21/2010 with effective date 3/29/11.(lpr)

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- 4/12/11 Specialty Matched Consultant Advisory Panel review 3/2011. No changes in policy statements. (mco)
- 4/17/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. References and Policy Guidelines updated. No change to policy statement.(lpr)
- 12/28/12 Added CPT codes 31647, 31648, 31649, 31651 to the Billing/Coding section for effective date 1/1/2013. Deleted CPT codes 0250T, 0251T, 0252T. (lpr)
- 4/16/13 Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review meeting 3/20/13. References added. No change to policy statement. (lpr)
- 5/13/14 Specialty matched consultant advisory panel review meeting 4/30/2014. No change to policy statement. Reference updated. (lpr)
- 4/28/15 Updated “Policy Guidelines.” Reference added. Specialty matched consultant advisory panel review 3/25/2015. No change to policy statement. (lpr)
- 4/29/16 Updated Policy Guidelines and Description sections. Revised the When Not Covered statement to indicate “all” situations to clarify intent. No change to policy statement or intent. Specialty Matched Consultant Advisory Panel review 3/30/2016. (lpr)
- 7/26/16 Policy Guidelines updated. Reference added. No change to policy statement. (lpr)
- 4/28/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. Reference added. No change to policy statement. (lpr)
- 7/28/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. Reference added. No change to policy statement. (lpr)
- 7/27/18 Reference added. (lpr)
- 4/30/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. No change to policy statement. (lpr)
- 4/28/20 Description, Policy Guidelines and References updated. Specialty Matched Consultant Advisory Panel review 3/31/2020. No change to policy statement. (eel)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.