

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 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.

In October 2008, the “IBV® Valve System” (Spiration, Inc, Redmond, WA) was approved by the FDA under the Humanitarian Device Exemption 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 3) 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.

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 one 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 January 2012, the Zephyr Endobronchial Valve has not been cleared by the FDA.

*****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** as a treatment of prolonged air leaks.

Endobronchial valves are considered **investigational** as a treatment for patients with COPD or emphysema.

Policy Guidelines

The only available data on endobronchial valves for treating persistent air leaks are uncontrolled trials

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with small numbers of heterogeneous patients. Data on the FDA-approved endobronchial valve device are particularly limited. A small case series using the FDA-approved valves for treating air leaks reported on 9 patients; valves were successfully placed in 7 of them. This evidence is not adequate to determine a risk/benefit ratio for this procedure, nor does it provide any evidence on comparisons with alternatives.

For patients with advanced emphysema, case series and a single unblinded RCT provide insufficient evidence that the technology improves the net health outcome. In the RCT, the magnitude of the improvements was of uncertain clinical significance, and the statistical significance was marginal for the majority of the comparisons. In addition, the numerous adverse events experienced by patients who received endobronchial valves raise concerns about the safety of the treatment.

In 2011, the British Thoracic Society published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults. The guidelines stated that sufficient evidence has not yet been demonstrated to recommend the routine use of endobronchial valves for treatment of emphysema.

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: 0250T, 0251T, 0252T

Code 0250T would be reported with a bronchoscopy code like 31622 or 31634.

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

Senior Medical Director Review 11/2010

Specialty Matched Consultant Advisory Panel review 3/2011

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.

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

Specialty Matched Consultant Advisory Panel review 3/2012

Policy Implementation/Update Information

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- 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)
- 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)

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.