Bronchial Valves

**Introduction**

In the chest, the lung sits in an airless sack called the pleural cavity or pleural space. The only air in the chest should be found within the lung itself. If the lung leaks air, the air can escape from the lung into the pleural space. If air leaks into the pleural space, the lung may be unable to adequately inflate, resulting in a collapsed lung or shallow, slow, or inadequate breathing. As a result, too little oxygen may get into the blood. Air leaks can occur because of disease, surgery, or injury. A type of one-way valve has been proposed as a way to try to keep air from leaking out of the lung. The umbrella-shaped device is placed in the airway and is intended to keep air from moving toward the air leak. This type of device is investigational (unproven). More studies are needed to see how well it works compared to standard treatments and to look at its overall safety.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Device Investigational

**Bronchial valves**

Bronchial 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 or emphysema

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31647</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe</td>
</tr>
<tr>
<td>31648</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe</td>
</tr>
<tr>
<td>31649</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>31651</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure(s))</td>
</tr>
</tbody>
</table>

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### Related Information

N/A

### Evidence Review
Description

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.

Background

Air Leaks

Proper lung functioning depends on the 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 trauma, high airway pressures induced during mechanical ventilation, lung surgery, and rupture of lung blebs or bullae, which may be congenital or the result of chronic obstructive pulmonary disease.

Treatment

Although an air leak from the lung into the pleural space may seal spontaneously, it often requires intervention. Techniques currently used to try to close air leaks include the following:

- Inserting a chest tube (tube thoracostomy) and using 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.

A bronchial 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 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.
**Emphysema**

In emphysematous chronic obstructive pulmonary disease, peripheral lung tissue may form bullae. These diseased portions of the lung ventilate poorly, cause air trapping, and hyperinflation, 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 chronic obstructive pulmonary disease 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.

**Summary of Evidence**

For individuals who have pulmonary air leaks who receive bronchial 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. 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 systemic 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02382614</td>
<td>Safety and Effectiveness of the Spiration Valve System (SVS) in Air Leaks (VAST)</td>
<td>200</td>
<td>Dec 2018 (suspended)</td>
</tr>
<tr>
<td>NCT02022683</td>
<td>A Multi-center, Prospective, Randomized, Controlled Trial of Endobronchial Valve Therapy vs. Standard of Care in Heterogeneous Emphysema (TRANSFORM)</td>
<td>97</td>
<td>Dec 2018 (long-term safety)</td>
</tr>
<tr>
<td>NCT01796392</td>
<td>Lung Function Improvement After Bronchoscopic Lung Volume Reduction With Pulmonx Endobronchial Valves Used in Treatment of Emphysema (LIBERATE)</td>
<td>183</td>
<td>Sep 2021 (long-term safety)</td>
</tr>
<tr>
<td>NCT01812447</td>
<td>A Prospective, Randomized, Controlled Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the Spiration® Valve System for the Single Lobe Treatment of Severe Emphysema (EMPROVE)</td>
<td>172</td>
<td>May 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

**Clinical Input Received from 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 in 2011. Input generally agreed that use of bronchial valves is investigational for treating emphysema. Regarding use of bronchial 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

In 2011, the British Thoracic Society published guidelines on advanced diagnostic and therapeutic flexible bronchoscopy in adults.\textsuperscript{15} The guidelines indicated that the evidence is insufficient to recommend routine use of bronchial valves for treatment of emphysema.

National Institute for Health and Care Excellence (NICE)

In December 2017, NICE issued the following recommendations on endobronchial valve insertion to reduce lung volume in emphysema:\textsuperscript{16}

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.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In October 2008, the Spiration® IBV 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 2. Bronchial Valves Approved by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Location</th>
<th>Date Approved</th>
<th>HDE/PMA No.</th>
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<tbody>
<tr>
<td>IBV® Valve System</td>
<td>Spiration, Inc</td>
<td>Redmond, WA</td>
<td>10/24/08</td>
<td>H060002</td>
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<tr>
<td></td>
<td>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).</td>
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<tr>
<td>Spiration® Valve System</td>
<td>Spiration, Inc</td>
<td>Redmond, WA</td>
<td>12/03/18</td>
<td>P180007</td>
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<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Location</td>
<td>Date Approved</td>
<td>HDE/PMA No.</td>
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<tr>
<td>One-way endobronchial valves indicated 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</td>
<td>Pulmonx Corporation</td>
<td>Redwood City, CA</td>
<td>06/18/15</td>
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<tr>
<td>Zephyr® Endobronchial Valve System</td>
<td>Pulmonx Corporation</td>
<td>Redwood City, CA</td>
<td>06/18/15</td>
<td>P180002</td>
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FDA: Food and Drug Administration, HDE: human device exemption; PMA: premarket approval application.

References


History

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<th>Comments</th>
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<tr>
<td>01/11/11</td>
<td>Add to Surgery Section - New policy created with literature search through October 2010; considered investigational.</td>
</tr>
<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with clinical input and a literature search through December 2011. References 10, 12 and 13 added; other references reordered. Policy</td>
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<td>Date</td>
<td>Comments</td>
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<tr>
<td>01/10/13</td>
<td>Coding update. CPT codes 0250T – 0252T deleted as of 12/31/12; these are replaced by 31647 – 31649, which are added to the policy, along with 31651, 31660 – 31661, all effective 1/1/13.</td>
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<td>04/16/13</td>
<td>Replace policy. Policy updated with a literature search through January 16, 2013. Reference 6 added; other references reordered. Policy statements unchanged. Codes 31660 and 31661 removed; they have been added to another policy and do not apply to this policy.</td>
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<tr>
<td>05/05/14</td>
<td>Annual Review. Policy updated with a literature search through January 7, 2014. References 2 and 8 added; other references reordered or removed. Policy statements unchanged.</td>
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</table>

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Email AppealsDepartmentInquiries@LifeWiseHealth.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7667 (TDD)
Complaint forms are available at

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