MEDICAL POLICY – 7.01.128
Bronchial Valves

BCBSA Ref. Policy: 7.01.128
Effective Date: Sept. 1, 2020
Last Revised: Aug. 4, 2020
Replaces: N/A
RELATE MEDICAL POLICIES: None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

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.

Policy Coverage Criteria
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>CPT</td>
<td></td>
</tr>
<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>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**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 in patients with lobar hyperinflation from severe or advanced emphysema.

Background

Pulmonary 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 (COPD).

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**

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 with patients experiencing 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.¹ 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 severity of airflow obstruction**

<table>
<thead>
<tr>
<th>Stages of Airflow Limitation</th>
<th>Severity Grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1 (mild): FEV₁ ≥ 80% predicted</td>
<td>Group A: low risk&lt;br&gt;0-1 exacerbation per year, not requiring hospitalization, fewer symptoms</td>
</tr>
<tr>
<td>GOLD 2 (moderate): 50% ≤ FEV₁ &lt;80% predicted</td>
<td>Group B: low risk&lt;br&gt;0-1 exacerbation per year, not requiring hospitalization, more symptoms</td>
</tr>
<tr>
<td>GOLD 3 (severe): 30% ≤ FEV₁ &lt;50% predicted</td>
<td>Group C: high risk</td>
</tr>
</tbody>
</table>

### Stages of Airflow Limitation

<table>
<thead>
<tr>
<th>Severity Grouping</th>
<th>Severity Grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥2 exacerbations per year, or one or more requiring</td>
<td>≥2 exacerbations per year, or one or more requiring</td>
</tr>
<tr>
<td>hospitalization, fewer symptoms</td>
<td>hospitalization, more symptoms</td>
</tr>
<tr>
<td>GOLD 4 (very severe): FEV1 &lt;30% predicted</td>
<td>Group D: high risk</td>
</tr>
</tbody>
</table>

### Bronchial Valves

Bronchial valves are synthetic devices deployed 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. 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 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.

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. 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 RCTs and 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. 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. The potential benefits of the procedure do not outweigh the demonstrated harms. 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 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>---------</td>
<td>------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT02382614&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Safety and Effectiveness of the Spiration Valve System (SVS) in Air Leaks (VAST)</td>
<td>200</td>
<td>Dec 2019 (suspended, interim analysis and potential modification)</td>
</tr>
<tr>
<td>NCT01796392&lt;sup&gt;a&lt;/sup&gt;</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>Feb 2023</td>
</tr>
<tr>
<td>NCT01812447&lt;sup&gt;a&lt;/sup&gt;</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>
<tr>
<td>NCT04186546&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Zephyr Valve Registry (ZEVR)</td>
<td>150</td>
<td>Dec 2024</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
<sup>a</sup> 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

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

The GOLD (2020) publication makes the following statements on lung volume reduction interventions:

• "In selected patients with heterogeneous or homogeneous emphysema and significant hyperinflation refractory to optimized medical care, surgical or bronchoscopic modes of lung volume reduction (e.g., endobronchial one-way valves, lung coils, or thermal ablation) may be considered."

• In select patients with advanced emphysema, bronchoscopic interventions reduce end-expiratory lung volume and improve exercise tolerance, quality of life and lung function at 6-12 months following treatment (Evidence Level A for endobronchial valves: well-designed RCTs with consistent findings in the intended population without any important limitations).

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:

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.

NICE guidance on the diagnosis and management of COPD (2018) included the following recommendations on lung volume reduction procedures:
Offer a respiratory review to assess whether a lung volume reduction procedure is a possibility for people with COPD when they complete pulmonary rehabilitation and at other subsequent reviews, if all of the following apply:

- They have severe COPD, with FEV1 less than 50% and breathlessness that affects their quality of life despite optimal medical treatment
- They do not smoke
- They can complete a 6-minute walk distance of at least 140 m (if limited by breathlessness).

At the respiratory review, refer the person with COPD to a lung volume reduction multidisciplinary team to assess whether lung volume reduction surgery or endobronchial valves are suitable if they have:

- Hyperinflation, assessed by lung function testing with body plethysmography and
- Emphysema on unenhanced CT chest scan and
- Optimized treatment for other comorbidities.

**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.
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 3. Bronchial Valve Systems Approved by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Location</th>
<th>Date Approved</th>
<th>HDE/PMA No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBV® Valve System</td>
<td>Spiration, Inc</td>
<td>Redmond, WA</td>
<td>10/24/08</td>
<td>H060002</td>
</tr>
<tr>
<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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spiration® Valve System</td>
<td>Spiration, Inc</td>
<td>Redmond, WA</td>
<td>12/03/18</td>
<td>P180007</td>
</tr>
<tr>
<td>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></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zephyr® Endobronchial Valve System</td>
<td>Pulmonx Corporation</td>
<td>Redwood City, CA</td>
<td>06/29/18</td>
<td>P180002</td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<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 statements unchanged.</td>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>
Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保障的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動。以保留您的健康保護或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lwa osawa konsèn kpvèt_kelisir lan atraver Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kenbe kpvèt kelisir ansante w la osawa pou yo ka ede w avek depans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaar ket naglao iti Napateg nga Impormasion. Daytoy a pakdaar mabalib nga adda ket naglao iti napateg nga impormasion maipanggep iti aplikasyon wiyon coverage babaen iti Premera Blue Cross. Daytoy ket mabalib dagiti importanta a pelsa iti daytoy a pakdaar. Mabalib nga adda rumbeng nga aramideny nga adda sakbay dagiti partikular a naituding nga adda aldaw tapo mapagtalaineyo iti coverage ti salun-atyo wiyen tulong kadagiti gastos. Adda karnbengayo a mangala iti daytoy nga impomasion ken tulong iti bukodyo a pagasaao nga awan ti bayadangyo. Tumawag ti numero nga osawa 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):