



**EFFECTIVE DATE:** 01|01|2016  
**POLICY LAST UPDATED:** 08|07|2018

## OVERVIEW

Bronchial 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 bronchopleural air leaks, as well as an alternative to lung volume reduction surgery in patients with lobar hyperinflation from severe or advanced emphysema.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### BlueCHiP for Medicare

Use of bronchial valves for the treatment of prolonged air leaks or for treatment of chronic obstructive pulmonary disease (COPD) or emphysema is considered not covered due to insufficient evidence to determine the effects of the technology on health outcomes.

### Commercial Products

Use of bronchial valves for the treatment of prolonged air leaks or for treatment of chronic obstructive pulmonary disease (COPD) or emphysema is considered not medically necessary due to insufficient evidence to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## BACKGROUND

Proper lung functioning depends on 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 a result of COPD.

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

- Inserting a chest tube (tube thoracostomy) and employing a water seal or 1-way valve to evacuate air collected in the pleural space and prevent it from re-accumulating
- Lowering airway pressures by adjusting the mechanical ventilator
- Using autologous blood patches
- Performing a thoracotomy with mechanical or chemical pleurodesis

A bronchial valve is a device that permits 1-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.

In emphysematous chronic obstructive pulmonary disease, 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 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.

Although some outcomes were statistically significant in favor of 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.

#### **CODING**

The following codes are not covered for BlueCHIP for Medicare and are not medically necessary for Commercial Products:

- 31647 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
- 31651 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])
- 31648 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
- 31649 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)

#### **RELATED POLICIES**

Lung Volume Reduction Surgery

#### **PUBLISHED**

Provider Update, November 2018  
Provider Update, September 2017  
Provider Update, September 2016

#### **REFERENCES**

1. Travaline JM, McKenna RJ, Jr., De Giacomo T, et al. Treatment of persistent pulmonary air leaks using endobronchial valves. *Chest*. Aug 2009;136(2):355-360. PMID 19349382

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
4. Scuirba FC, Ernst A, Herth FJ, et al. A randomized study of endobronchial valves for advanced emphysema. *N Engl J Med.* Sep 23 2010;363(13):1233-1244. PMID 20860505
5. Herth FJ, Noppen M, Valipour A, et al. Efficacy predictors of lung volume reduction with Zephyr valves in a European cohort. *Eur Respir J.* Jun 2012;39(6):1334-1342. PMID 22282552
6. Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire. *Respir Med.* Sep 1991;85 Suppl B(Suppl B):25-31; discussion 33-27. PMID 1759018
7. Valipour A, Herth FJ, Burghuber OC, et al. Target lobe volume reduction and COPD outcome measures after endobronchial valve therapy. *Eur Respir J.* Jul 11 2013. PMID 23845721
8. Davey C, Zoumot Z, Jordan S, et al. Bronchoscopic lung volume reduction with endobronchial valves for patients with heterogeneous emphysema and intact interlobar fissures (the BeLieVeR-HIFi study): a randomised controlled trial. *Lancet.* Sep 12 2015;386(9998):1066-1073. PMID 26116485
9. 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
10. 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 2200315
11. van Agteren JE, Hnin K, Grosser D, et al. Bronchoscopic lung volume reduction procedures for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev.* Feb 23 2017;2:CD012158. PMID 28230230

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

