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POLICY LAST UPDATED: 02|03|2016

OVERVIEW

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 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 and Commercial Products

Use of endobronchial valves for the treatment of prolonged air leaks or for treatment of chronic obstructive pulmonary disease 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. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable not medically necessary 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 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 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.

An endobronchial 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 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.

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 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 nonsurgical alternative to LVRS.

Although some outcomes were statistically significant in favor of endobronchial valve treatment, the magnitude of the difference was generally of uncertain clinical significance. Moreover, the numerous adverse events experienced by patients who received endobronchial 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

BlueCHiP for Medicare and Commercial products

The following codes are not medically necessary:

31647
31651
31648
31649

RELATED POLICIES

Lung Volume Reduction Surgery

PUBLISHED

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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, Serman 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. Scieurba 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 22003155

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