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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, August 2020
Provider Update, July 2019
Provider Update, November 2018
Provider Update, September 2017
Provider Update, September 2016

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