

Current Effective Date: 2/6/25

Status: Approved

Reviewed by Medical Policy Subcommittee: 8/16/23, 2/6/25

Reviewed Dates: 8/16/23, 2/1/24, 1/23/25

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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

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### **Bronchial Valve Policy**

#### **Indication/Usage:**

Bronchial valves (Spiration Valve System and Zephyr Valve System) are synthetic devices inserted 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 and fluid to escape from the diseased area of the lung. They have been used 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 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. Based on the condition of the individual's lungs, multiple valves may be implanted. Endobronchial valves (EBV) have been proposed as a less invasive alternative to lung volume reduction surgery (LVRS) in emphysema, where damaged tissue is surgically removed to make the lungs smaller allowing them to function better

## **Medical Indications for Authorization Commercial and Medicare Members**

1. FDA-approved endobronchial valve is considered medically necessary for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema when ALL the following criteria has been met.

- Age 40 to 75 years
- The member has been nonsmoking for four months prior to initial evaluation
- Patient has not responded to adequate medical therapy including pulmonary rehabilitation, oxygen supplementation, and optimal medication management
- A supervised pulmonary rehabilitation program was completed less than or equal to six months prior to initial evaluation
- FEV1 between 15%-45% of predicted value at initial evaluation
- Little or no collateral ventilation (CV) as determined using the Chartis System
- 6-minute walk distance (MWD) is >100 and <500m
- Absence of contradictions listed in the Limitations section

There is currently no NCD or LCD per CMS

### **CPT Codes**

- 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
- 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
- 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

### **Limitations**

Bronchial valves are contraindicated for all conditions listed below

- Individuals who are unable to tolerate bronchoscopic procedures
- Allergy to device materials (nitinol, nickel, titanium or silicone)
- Myocardial infarction within 90 days of initial evaluation or diagnosis of congestive heart failure
- Two or more COPD exacerbations or two or more episodes of pneumonia within the previous 90 days; or
- Prior lung transplant, lung volume reduction surgery (LVRS), bullectomy or Lobectomy

### **Coverage Decisions**

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

## Plans Covered By This Policy

Commercial and Medicare

Self-funded Commercial groups refer to plan document for coverage

## Sources Reviewed

Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2020 Global Strategy for Prevention, Diagnosis, and Management of COPD. <https://goldcopd.org/gold-reports>

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