



MASSACHUSETTS

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Medical Policy Bronchial Valves

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)

Policy Number: 313

BCBSA Reference Number: 7.01.128 (For Plan internal use only)

NCD/LCD: N/A

Related Policiesⁱ

- Lung Volume Reduction Surgery for Severe Emphysema, #[364](#)
- Outpatient Pulmonary Rehabilitation, #[136](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Endobronchial valves (Zephyr Valve System™) may be considered **MEDICALLY NECESSARY** for the treatment of severe emphysema and hyperinflation as an alternative to lung volume reduction surgery:

- Patient has not responded to adequate medical therapy including pulmonary rehabilitation, oxygen supplementation, and optimal medication management, **AND**
- Forced expiratory volume in one second (FEV1) between 15%-45%, **AND**
- 6-minute walk distance (MWD) is >100 and <500m, **AND**
- Age 40-75 years, **AND**
- Patient has little to no collateral ventilation (as determined using the Chartis System and Quantitative lung CT analysis), **AND**
- Does not have any of the following:
 - History of recurrent bronchiectasis, **AND**
 - Prior lung transplant, lung volume reduction surgery, bullectomy or lobectomy,
 - Heart attack or decompensated congestive heart failure within the last 6 months, **AND**
 - Unstable/uncontrolled ischemic heart disease or unstable/ uncontrolled heart arrhythmia, **AND**
 - Allergy to nickel, titanium, or silicone, **AND**
 - Severe hypoxemia or hypercapnia or respiratory failure.

Bronchial valves are considered **INVESTIGATIONAL** in all other scenarios including for the treatment of prolonged air leaks.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

| | Outpatient |
|---------------------------------------|--|
| Commercial Managed Care (HMO and POS) | Prior authorization is not required . |
| Commercial PPO and Indemnity | Prior authorization is not required . |
| Medicare HMO Blue SM | Prior authorization is not required . |
| Medicare PPO Blue SM | Prior authorization is not required . |

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

| CPT codes: | Code Description |
|------------|---|
| 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 (List separately in addition to code for primary procedure) |
| 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]) |

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Codes

| ICD-10-CM Diagnosis codes: | Code Description |
|----------------------------|---|
| J43.0 | Unilateral pulmonary emphysema [MacLeod's syndrome] |
| J43.1 | Panlobular emphysema |
| J43.2 | Centrilobular emphysema |
| J43.8 | Other emphysema |
| J43.9 | Emphysema, unspecified |

Description

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 a result of chronic obstructive pulmonary disease (COPD).

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

| Stages of Airflow Limitation | Severity Grouping |
|--|---|
| GOLD 1 (mild): FEV1 ≥ 80% predicted | Group A: low risk 0-1 exacerbation per year, not requiring hospitalization, fewer symptoms |
| GOLD 2 (moderate): 50% ≤ FEV1 < 80% predicted | Group B: low risk 0-1 exacerbation per year, not requiring hospitalization, more symptoms |
| GOLD 3 (severe): 30% ≤ FEV1 < 50% predicted | Group C: high risk ≥ 2 exacerbations per year, or one or more requiring hospitalization, fewer symptoms |
| GOLD 4 (very severe): FEV1 < 30% predicted | Group D: high risk ≥ 2 exacerbations per year, or one or more requiring hospitalization, more symptoms |

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

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.

Summary of Evidence

In June of 2018, the FDA approved Zephy Endobronchial Valve system for the treatment of severe emphysema with hyperinflation. For individuals who have severe or advanced emphysema who receive bronchial valves, the evidence includes 3 Pivotal RCTs, several meta-analyses, and systematic 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. Current standard medical management includes maximum pulmonary rehabilitation, medication management and surgical procedures such as lung transplantation, bullectomy and lung volume reduction surgery (LVRS). Studies evaluating LVRS in patients with severe emphysema demonstrate improvements in forced expiratory volume (FEV), exercise tolerance, and quality of life. LVRS is associated with a relatively high risk of adverse events such as pneumothorax and is not appropriate for patients who are suboptimal candidates for anesthesia.

A number of randomized controlled trials including the Liberate trial (2019), Transform trial (2017), Impact trial (2016), as well as studies published by the National Emphysema Treatment Trial research group, evaluated outcomes for over 500 patients to determine change in baseline status for lung function, exercise tolerance and quality of life for up to 12 months after endobronchial valve placement. Each study required that patients have severe emphysema with hyperinflation, have had an adequate trial of optimal medical management including maximum pulmonary rehabilitation, FEV1 between 15% and 45%, limited to no collateral ventilation (based on the Chartis assessment), and 6-minute walk distance (6MWD) of less than 450 meters. Results from the Transform study showed that 55.4% of patients treated with EBV had an increased FEV1 by 12% or more compared to 6.5% of control group. The Liberate trial determined that 44.7% of patients treated with EBV demonstrated 15% or greater improvement in FEV1 compared with 6.5% of standard of care group. Similar improvements in outcomes were reported for 6MWD and quality of life functions for the EBV groups compared to patients treated with standard of care.

A recent meta-analysis conducted by Labarca (2019) determined that Zephyr valves provided significant and clinically meaningful short-term improvements in carefully selected patients with severe emphysema

and little to no collateral ventilation when compared to standard of care noting that endobronchial valves provide an important benefit for patients with high risks of comorbidities or for patients who are deemed unsuitable candidates for lung volume reduction surgery.

All of the available studies highlight the concern for adverse events including the risk for pneumothorax and infection or need for removal of the valves. For patients with severe disease, current standards of care are lung transplantation, lung volume reduction surgery, bullectomy, or lobectomy, all of which have demonstrated similar or worse risks of surgical or post-surgical complications including pneumothorax and infection. While lung volume reduction surgery is considered the gold standard for treating severe disease, the procedure involves removing portions of diseased lung which has proven to be irreversible and, in some cases, leads to further complications and negative outcomes.

Newer studies are available assessing the risk of pneumothorax in endobronchial valve placement and outline standard of care management options to reduce risk of adverse events and improve outcomes. These studies recommend a 3-day inpatient post procedure stay to monitor patients and include specific exclusion criteria for suboptimal candidates. Based on the outcomes of the randomized controlled trials and published guidelines from the American Lung Association as well as the Global Initiative for Chronic Obstructive Lung disease (GOLD), endobronchial valve placement has been identified as an effective and appropriate alternative to LVRS. Providers have been educated to submit documentation to a national multicenter registry to track outcomes and improvements in patient's lung function and quality of life. Many multicenter registries have provided clinical documentation demonstrating patient improvements. The evidence is sufficient to determine net health outcomes.

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. This evidence is inadequate to determine the impact of this technology on the net health outcome.

Policy History

| Date | Action |
|----------------|---|
| 8/2022 | Annual policy review. Policy statements unchanged. |
| 6/2021 | New medically necessary indication added. Clarified coding information. References added. 6/2021. |
| 8/2020 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 8/2019 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 6/2018 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 8/2017 | Annual policy review. Endobronchial changed to Bronchial in policy and title. |
| 8/2015 | Annual policy review. Revised policy statement to say "all" situations to clarify the intent. 8/1/2015. |
| 5/2015 | Policy statement clarified. Annual policy review. New references added. Clarified coding language. |
| 5/2014 | Annual policy review. New references added. |
| 4/2013 | Annual policy review. New references added. |
| 2/2012 | Updated to add new CPT codes 31648, 31649 and 31651. Remove deleted CPT codes 0250T-0252T. |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements. |
| 4/2011 | Reviewed - Medical Policy Group – Cardiology and Pulmonology. No changes to policy statements. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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Endnotes

ⁱ Based on expert opinion