EFFECTIVE DATE: 01|01|2016
POLICY LAST UPDATED: 07|05|2023

OVERVIEW
Bronchial valves are synthetic devices deployed with bronchoscopy into ventilatory airways of the lung to control airflow. They have been investigated for use in individuals who have prolonged bronchopleural air leaks and in individuals with lobar hyperinflation from severe or advanced emphysema.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
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 that the effects of the technology results in an improvement in the net 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 that the effects of the technology results in an improvement in the net 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
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.

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.

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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe or advanced emphysema with little or no collateral ventilation between target and ipsilateral lobe who receive bronchial valves, the evidence includes a prospective cohort study with patient-reported outcomes, randomized controlled trials (RCTs), 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. However, confidence in these results is low due to study limitations including a lack of blinding and wide confidence intervals around estimates of effect. Across studies, there was an increased risk of serious procedure-related adverse events compared to usual care, including pneumothorax occurring in up to 27% of patients. A RCT (CELEB) that compared bronchial valves to LVRS in 80 individuals found no statistically significant difference between treatment groups on the primary outcome (change from baseline to 12 months on the iBODE instrument, -0.27 (-0.62 to 1.17); P =.54). Notably, the magnitude of change from baseline for both groups on the i-BODE was below the 1.5-point difference considered by the study investigators to be sufficiently clinically important. Of 4 secondary outcomes reported, only the CAT (a measure of health status) differed significantly between groups and favored the LVRS arm with a magnitude of difference above the MCID threshold of 2 points (mean difference from baseline -6 [2 to 9]). The trial was limited by lack of participant blinding, high loss to follow-up, choice of a composite primary outcome, and evidence of selective outcome reporting. The trial's results do not support a conclusion that bronchial valves are associated with less procedure-related morbidity than LVRS. More participants in the bronchial valve group required additional procedures post-intervention,

including 4 (8.5%) who went on to LVRS. Additionally, because it was designed to assess comparative effectiveness of bronchial valves and LVRS, the trial does not address existing gaps in the evidence on bronchial valves compared to medical management, the comparison of interest for this evidence review. In a prospective cohort study of patient-reported outcomes 1 year following treatment, 74.8% were satisfied with the treatment and 10.9% were unsatisfied, 52.6% were satisfied with the reduction in their symptoms after treatment and 24.9% were unsatisfied, and 91.4% said they would recommend the treatment to other patients. Confidence in these findings is limited by the study's uncontrolled design and high loss to follow-up (29.9%). The potential benefits of the procedure do not outweigh the demonstrated harms. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Regulatory Status
In October 2008, the Spiration® IBV Valve System (Spiration) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (H060002) process for use in controlling prolonged air leaks of the lung or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery. An air leak present on postoperative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: (1) continuous, (2) present during the normal inhalation phase of inspiration, or (3) present on normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Use of the Intrabronchial Valve System is limited to 6 weeks per prolonged air leak.

Two bronchial valve systems are FDA approved for treatment of patients with severe emphysema. In June 2018, FDA granted the Zephyr Valve system breakthrough device status with expedited approval for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. In December 2018, FDA approved the Spiration Valve System for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation.

CODING

The following codes are not covered for Medicare Advantage Plans 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

Not applicable

PUBLISHED

Provider Update, September 2023
Provider Update, November 2022
Provider Update, August 2021
Provider Update, August 2020
Provider Update, July 2019

REFERENCES

1. Centers for Disease Control and Prevention. Chronic Obstructive Pulmonary Disease (COPD). Data and Statistics. 2021. https://www.cdc.gov/copd/data.html. Accessed April 25, 2023.
2. Xu JQ, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2018. NCHS Data Brief, Number 355. Hyattsville, MD: National Center for Health Statistics; 2020. https://www.cdc.gov/nchs/data/databriefs/db355-h.pdf. Accessed April 28, 2023.
3. Zarrabian B, Mirsaeidi M. A Trend Analysis of Chronic Obstructive Pulmonary Disease Mortality in the United States by Race and Sex. Ann Am Thorac Soc. Jul 2021; 18(7): 1138-1146. PMID 33347376
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2022 Global Strategy for Prevention, Diagnosis, and Management of COPD. https://goldcopd.org/gold-reports/. Accessed April 24, 2023.
5. Travaline JM, McKenna RJ, De Giacomo T, et al. Treatment of persistent pulmonary air leaks using endobronchial valves. Chest. Aug 2009; 136(2): 355-360. PMID 19349382
6. 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): 1243-9. PMID 23434254
7. 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): 270-3. PMID 21172529
8. Eberhardt R, Slebos DJ, Herth FJF, et al. Endobronchial Valve (Zephyr) Treatment in Homogeneous Emphysema: One-Year Results from the IMPACT Randomized Clinical Trial. Respiration. NA 2021; 100(12): 1174-1185. PMID 34350884
9. 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
10. Criner GJ, Sue R, Wright S, et al. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (LIBERATE). Am J Respir Crit Care Med. Nov 01 2018; 198(9): 1151-1164. PMID 29787288
11. Dransfield MT, Garner JL, Bhatt SP, et al. Effect of Zephyr Endobronchial Valves on Dyspnea, Activity Levels, and Quality of Life at One Year. Results from a Randomized Clinical Trial. Ann Am Thorac Soc. Jul 2020; 17(7): 829-838. PMID 32223724
12. Kemp SV, Slebos DJ, Kirk A, et al. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (TRANSFORM). Am J Respir Crit Care Med. Dec 15 2017; 196(12): 1535-1543. PMID 28885054
13. Valipour A, Slebos DJ, Herth F, et al. Endobronchial Valve Therapy in Patients with Homogeneous Emphysema. Results from the IMPACT Study. Am J Respir Crit Care Med. Nov 01 2016; 194(9): 1073-1082. PMID 27580428
14. Klooster K, ten Hacken NH, Hartman JE, et al. Endobronchial Valves for Emphysema without Interlobar Collateral Ventilation. N Engl J Med. Dec 10 2015; 373(24): 2325-35. PMID 26650153
15. 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): 1066-73. PMID 26116485
16. 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- 42. PMID 22282552
17. Sciurba 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): 1233-44. PMID 20860505
18. National Institute for Health and Care Excellence. Chronic obstructive pulmonary disease in over 16s: Diagnosis and management. Available at: https://www.nice.org.uk/guidance/ng115/chapter/Recommendations#managing-stable-copd. Accessed April 24, 2023.
19. van Geffen WH, Slebos DJ, Herth FJ, et al. Surgical and endoscopic interventions that reduce lung volume for emphysema: a systemic review and meta-analysis. Lancet Respir Med. Apr 2019; 7(4): 313-324. PMID 30744937

20. Labarca G, Uribe JP, Pacheco C, et al. Bronchoscopic Lung Volume Reduction with Endobronchial Zephyr Valves for Severe Emphysema: A Systematic Review and Meta-Analysis. Respiration. NA 2019; 98(3): 268-278. PMID 31117102
21. Buttery S, Kemp SV, Shah PL, et al. CELEB trial: Comparative Effectiveness of Lung volume reduction surgery for Emphysema and Bronchoscopic lung volume reduction with valve placement: a protocol for a randomised controlled trial. BMJ Open. Oct 17 2018; 8(10): e021368. PMID 30337307
22. Buttery SC, Banya W, Bilancia R, et al. Lung volume reduction surgery versus endobronchial valves: a randomised controlled trial. Eur Respir J. Apr 2023; 61(4). PMID 36796833
23. 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): 288-97. PMID 25321447
24. Li S, Wang G, Wang C, et al. The REACH Trial: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration(R) Valve System in the Treatment of Severe Emphysema. Respiration. 2019; 97(5): 416-427. PMID 30554211
25. Criner GJ, Delage A, Voelker K, et al. Improving Lung Function in Severe Heterogenous Emphysema with the Spiration Valve System (EMPROVE). A Multicenter, Open-Label Randomized Controlled Clinical Trial. Am J Respir Crit Care Med. Dec 01 2019; 200(11): 1354-1362. PMID 31365298
26. U.S. Food & Drug Administration. Spiration Valve System. Summary of Safety and Effectiveness Data. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180007B.pdf. Accessed April 22, 2023.
27. Hartman JE, Klooster K, Ten Hacken NHT, et al. Patient Satisfaction and Attainment of Patient-Specific Goals after Endobronchial Valve Treatment. Ann Am Thorac Soc. Jan 2021; 18(1): 68-74. PMID 32881586
28. National Institute for Health and Care Excellence. Endobronchial valve insertion to reduce lung volume in emphysema (2017). Available at: https://www.nice.org.uk/guidance/IPG600/chapter/1-Recommendations. Accessed April 22, 2023.