Corporate Medical Policy

Endobronchial Valves

File Name: endobronchial_valves
Origination: 11/2010
Last Review: 3/2024

Description of Procedure or Service

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 broncho-pleural air leaks and in patients with lobar hyperinflation from severe or advanced emphysema.

An endobronchial valve permits one-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 and mucus to escape from the diseased area of the lung. They have been investigated for use in patients who have prolonged bronchopleural air leaks after lung resection and in patients with lobar hyperinflation from severe or advanced emphysema as an alternative to lung volume reduction surgery (LVRS) and lung transplantation.

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 use of bronchial valves to treat emphysema is based on the improvement observed in patients who have undergone (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 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 absence 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 (e.g., SeleCT). After 45 days post-procedure, residual volume can provide information on whether lung volume reduction has been achieved successfully.

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.

Currently, 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. The two valve systems differ in the mechanism by which the one way valve is created, the Zephyr a duckbill shape and the Spiration an umbrella shape.

Related Policies:
Lung and Lobar Transplantation
Lung Volume Reduction Surgery

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for endobronchial valves when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Endobronchial Valves are covered

1. Endobronchial valve placement with the FDA approved Zephyr® or Spiration® Valve System may be considered **medically necessary** for the treatment of severe emphysema when ALL of the following criteria are met:

- The patient's dyspneic symptoms are poorly controlled or activities of daily living are markedly restricted despite maximal medical management, AND
- Provider attestation that the patient has attended or enrolled in a pulmonary rehabilitation program, AND
- Age 40 to 75 years; AND
- Stable with ≤20mg prednisone (or equivalent) daily; AND
- Forced expiratory volume (FEV1) between 15% and 45% of predicted value at initial evaluation; AND
- 6-minute walking distance (6MWD) ≥100m and <500m; AND
- There is little to no interlobar collateral ventilation as determined by ≥ 90% completeness of the fissure separating the target lobe and the adjacent lobe; fissure completeness scores can be obtained using quantitative CT analysis systems (StratX for Zephyr valves or SeleCT for Spiration valves); OR
    - If the fissure separating the target lobe and the adjacent lobe is <90% complete on quantitative CT analysis systems, the lack of collateral ventilation must be confirmed by using the Chartis system (a measurement device used during bronchoscopy and prior to placement of the valves)

- Abstinence from smoking of any kind for 4 consecutive months prior to initial evaluation, and throughout the evaluation for the procedure; AND
- Valve placement will be performed by a provider who has completed procedure and valve-specific training.

2. Endobronchial valves may be considered **medically necessary** for the treatment of prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery.

When Endobronchial Valves are not covered

Endobronchial valves are considered **investigational** in all other situations for the treatment of emphysema, including but not limited to patients:

- who do not meet the criteria in the when covered section.
- who have previously undergone ipsilateral lung volume reductive surgery or lung/lobar transplant.
- in whom bronchosopic procedures are contraindicated.
- with evidence of active pulmonary infection.
- with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, unless being treated by an allergist.
- with large bullae encompassing greater than 30% of either lung.

Policy Guidelines

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.

For individuals who have severe or advanced emphysema who receive bronchial valves, the evidence includes 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, although 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. The potential benefits of the procedure are felt to outweigh the demonstrated harms in patients with advanced and medically refractory emphysema, and offer a less invasive alternative to lung volume reduction surgery.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *31647, 31648, 31649, 31651*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration. IBV® Valve System. Summary of safety and probable benefit. Available online: http://www.accessdata.fda.gov/cdrh_docs/pdf6/H060002b.pdf. Last accessed October 26, 2010.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 11/11/10

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/9/12

Specialty Matched Consultant Advisory Panel review 3/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/14/13

Specialty Matched Consultant Advisory Panel review 3/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 2/13/14

Specialty Matched Consultant Advisory Panel review 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 3/12/15

Specialty Matched Consultant Advisory Panel review 3/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/11/15

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Specialty Matched Consultant Advisory Panel review 3/2017

van Agteren JE, Hnin K, Grosser D, Carson KV, Smith BJ. Bronchoscopic lung volume reduction procedures for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2017 Feb 23;2:[CD012158.] [doi: 10.1002/14651858.CD012158.pub2.] Available from: http://www.nlm.nih.gov/citingmedicine

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/8/17

Specialty Matched Consultant Advisory Panel review 3/2018

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Specialty Matched Consultant Advisory Panel review 3/2019

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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. Accessed May 9, 2019.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.128, 6/13/19

Specialty Matched Consultant Advisory Panel review 3/2020

US Food & Drug Administration (FDA). Device approvals, Spiration valve system-P180007. http://www.fda.gov. Accessed March 11, 2021 https://www.fda.gov/medical-devices/recently-approved-devices/spiration-valver-system-p180007

US Food & Drug Administration (FDA). Device Approvals, Zephyr endobronchial valve system-P180002. Current as of July 24, 2018. Accessed March 11, 2021 https://www.fda.gov/medical-devices/recently-approved-devices/zephyrr-endobronchial-valve-system-p180002

Dransfield MT, Garner JL, Bhatt SP, et al . LIBERATE Study Group:. 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. 2020 Jul;17(7):829-838.

Criner GJ, Sue R, Wright S, et al. LIBERATE Study Group. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (LIBERATE). Am J Respir Crit Care Med. 2018 Nov 1;198(9):1151-1164.

Kemp SV, Slebos DJ, Kirk A, et al. TRANSFORM Study Team *. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (TRANSFORM). Am J Respir Crit Care Med. 2017 Dec 15;196(12):1535-1543.

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. 2019 Apr;7(4):313-324.

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Specialty Matched Consultant Advisory Panel review 3/2021

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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 randomized controlled trial. BMJ Open. Oct 17 2018; 8(10): e021368. PMID 30337307

Specialty Matched Consultant Advisory Panel review 3/2024

Medical Director review 3/2024

Policy Implementation/Update Information

12/21/10	New policy issued. Endobronchial valves are considered investigational as a treatment of prolonged air leaks. Endobronchial valves are considered investigational as a treatment for patients with COPD or emphysema. Notice given 12/21/2010 with effective date 3/29/11.(lpr)
4/12/11	Specialty Matched Consultant Advisory Panel review 3/2011. No changes in policy statements. (mco)
4/17/12	Specialty Matched Consultant Advisory Panel review 3/21/2012. References and Policy Guidelines updated. No change to policy statement.(lpr)
12/28/12	Added CPT codes 31647, 31648, 31649, 31651 to the Billing/Coding section for effective date 1/1/2013. Deleted CPT codes 0250T, 0251T, 0252T. (lpr)
4/16/13	Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review meeting 3/20/13. References added. No change to policy statement. (lpr)
5/13/14	Specialty matched consultant advisory panel review meeting 4/30/2014. No change to policy statement. Reference updated. (lpr)
4/28/15	Updated "Policy Guidelines." Reference added. Specialty matched consultant advisory panel review 3/25/2015. No change to policy statement. (lpr)
4/29/16	Updated Policy Guidelines and Description sections. Revised the When Not Covered statement to indicate "all" situations to clarify intent. No change to policy statement or intent. Specialty Matched Consultant Advisory Panel review 3/30/2016. (lpr)
7/26/16	Policy Guidelines updated. Reference added. No change to policy statement. (lpr)
4/28/17	Specialty Matched Consultant Advisory Panel review 3/29/2017. Reference added. No change to policy statement. (lpr)
7/28/17	Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)

4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. Reference added. No change to policy statement. (lpr)

7/27/18 Reference added. (lpr)

4/30/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. No change to policy statement. (lpr)

4/28/20 Description, Policy Guidelines and References updated. Specialty Matched Consultant Advisory Panel review 3/31/2020. No change to policy statement. (eel)

5/18/21 Description, When Covered, When Not Covered, and Policy Guidelines sections updated to reflect coverage criteria. References added. Policy statement changed to medically necessary for emphysema with criteria and persistent air leaks. Specialty Matched Consultant Advisory Panel review 3/2021. Medical Director review 4/2021. (bb)

3/31/22 Made the following updates to When Covered: Removed "Patient has completed a pulmonary rehabilitation program prior to valve placement", "Body mass index (BMI) less than 35kg/m2", and "There is little to no interlobar collateral ventilation as determined using the Chartis (Zephyr) or SeleCT (Spiration) systems". Added "Provider attestation that the patient has attended or enrolled in a pulmonary rehabilitation program" and "There is little to no interlobar collateral ventilation as determined by ≥ 90% completeness of the fissure separating the target lobe and the adjacent lobe; fissure completeness scores can be obtained using quantitative CT analysis systems (StratX for Zephyr valves or SeleCT for Spiration valves); OR If the fissure separating the target lobe and the adjacent lobe is <90% complete on quantitative CT analysis systems, the lack of collateral ventilation must be confirmed by using the Chartis system (a measurement device used during bronchoscopy and prior to placement of the valves)." Updated Bullet #8 under When covered to read "Abstinence from smoking of any kind". Made the following updates to When Not Covered: Removed "with diffuse homogenous emphysema", updated bullet #5 to add "unless being treated by an allergist". Specialty Matched Consultant Advisory Panel review 3/2022. References added. Medical Director review 3/2022 (tt)

3/31/23 References updated. Specialty Matched Consultant Advisory Panel review 3/2023. Medical Director review 3/2023. No change to policy statement. (tt)

4/1/24 Description, Policy Guidelines, and References updated. Specialty Matched Consultant Advisory Panel review 3/2024. Medical Director review 3/2024. No change to policy statement. (tt)