MEDICAL POLICY

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP-1.122

Original Issue Date (Created):	**9/1/2011**
Most Recent Review Date (Revised):	**4/17/2020**
Effective Date:	**7/1/2020**

I. POLICY

TOP

Bronchial valves are considered **investigational** in situations including, but not limited to:

- Treatment of prolonged air leaks; **and**
- Treatment for patients with chronic obstructive pulmonary disease (COPD) or emphysema.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

Only one endobronchial valve device has approval from the U.S. Food and Drug Administration (FDA) through the Humanitarian Device Exemption (HDE) process for use in prolonged pulmonary air leaks.

Cross-reference:

MP-1.025 Lung Volume Reduction Surgery for Severe Emphysema

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.128, Endobronchial Valves. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP-1.122

III. DESCRIPTION/BACKGROUND

TOP

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. 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 as an alternative to lung volume reduction surgery in patients with lobar hyperinflation from severe or advanced emphysema.

Emphysema

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.

Treatment

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.

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. FDA product code: OAZ.

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP-1.122

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. FDA product code: NJK.

Table 1. Bronchial Valves Approved by FDA

Device	Manufacturer	Location	Date Approved	HDE/PMA No.
IBV® Valve System **To control 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 (LVRS).**	Spiration, Inc	Redmond, WA	10/24/08	**H060002**
Spiration® Valve System **One-way endobronchial valves indicated for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low**	Spiration, Inc	Redmond, WA	12/03/18 06/18/15	**P180007**

collateral ventilation **Breakthrough designation status**				
Zephyr® Endobronchial Valve System **Implantable bronchial valves indicated 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** **Breakthrough designation status**	**Pulmonx Corporation**	**Redwood City, CA**	**06/29/18** **05/04/17**	**P180002**

FDA: Food and Drug Administration, HDE: human device exemption; PMA: premarket approval application.

IV. RATIONALE

TOP

Summary of Evidence

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 the effects of the technology on health outcomes.

For individuals who have severe or advanced emphysema who receive bronchial valves, the evidence includes 11 RCTs and 3 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, but there was a greater risk of serious adverse events compared to usual care. Because of limitations in study designs, especially a lack of blinding, significant heterogeneity across studies on some measures, and a higher risk of serious adverse events, with up to 29% of patients experiencing pneumothorax, the evidence is insufficient to determine that the technology improves the net health outcome.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Endobronchial valves are considered investigational; therefore, not covered:

CPT Codes®								
31647	31648	31649	31651					

IX. REFERENCES

TOP

1. *Travaline JM, McKenna RJ, Jr., De Giacomo T, et al. Treatment of persistent pulmonary air leaks using endobronchial valves. Chest. Aug 2009;136(2):355-360. PMID 19349382.*
2. *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):1243-1249. PMID 23434254.*
3. *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):270-273. PMID 21172529.*
4. *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.*
5. *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.*
6. *van Geffen, WW, Slebos, DD, Herth, FF, Kemp, SS, Weder, WW, Shah, PP. Surgical and endoscopic interventions that reduce lung volume for emphysema: a systemic review and meta-analysis. Lancet Respir Med, 2019 Feb 13;7(4). PMID 30744937.*
7. *Criner, GG, Sue, RR, Wright, SS, Dransfield, MM, Rivas-Perez, HH, Wiese, TT, Sciurba, FF, Shah, PP, Wahidi, MM, de Oliveira, HH, Morrissey, BB, Cardoso, PP, Hays, SS, Majid, AA, Pastis, NN, Kopas, LL, Vollenweider, MM, McFadden, PP, Machuzak, MM, Hsia, DD, Sung, AA, Jarad, NN, Kornaszewska, MM, Hazelrigg, SS, Krishna, GG, Armstrong, BB, Shargill, NN, Slebos, DD, Criner, GG, Cordova, FF, Desai, PP, Marchetti, NN, Kim, VV, Shenoy, KK, Travaline, JJ, Thomas, JJ, Criner, LL, Sue, RR, Wright, SS, Thornburg, AA, Thomas, TT, Dransfield, MM, Bhatt, SS, Wells, JJ, Seabron-Harris, NN, Rivas-Perez, HH, Gauhar, UU, Wiese, TT, Despirito, CC, Sciurba, FF, Bon Field, JJ, Chandra, DD, Leader, JJ, Semaan, RR, Ledezma, CC, Shah, PP, Kemp, SS, Garner, JJ, Aboelhassan, AA, Srikanthan, KK,*

Tenda, EE, Abraham, AA, Sim, CC, Wahidi, MM, Mahmood, KK, Shofer, SS, Coles, KK, de Oliveira, HH, Oliveira, GG, Machado, BB, Benedetto, II, Svartman, FF, de Macedo Neto, AA, Schreiner, LL, Vieira, TT, Morrissey, BB, Yoneda, KK, Tham, TT, Tompkins, DD, Guerreiro Cardoso, PP, Athanazio, RR, Nominando, FF, Rached, SS, Cassimiro, LL, Hays, SS, Seeley, EE, Shrestha, PP, Dincheva, GG, Majid, AA, Alape-Moya, DD, Parikh, MM, Paton, AA, Agnew, AA, Pastis, NN, Strange, CC, Beiko, TT, Woodford, DD, Blanton, MM, Kopas, LL, Connolly, TT, Santacruz, JJ, Shah, BB, Vollenweider, MM, Herrera, LL, Khan, RR, Sernulka, KK, McFadden, PP, Barbers, RR, Hernandez, MM, Machuzak, MM, Almeida, FF, Cicenia, JJ, Gildea, TT, Mehta, AA, Sethi, SS, Meli, YY, Hsia, DD, Casaburi, RR, Stringer, WW, Diaz, LL, Sung, AA, Ramsey, MM, Van Wert, RR, Morris, KK, Jarad, NN, Batchelor, TT, Sequeiros, II, Tucker, KK, Kornaszweska, MM, Fallouh, HH, Sabit, RR, Naase, HH, George, JJ, Salimian, AA, Dyer, HH, Hazelrigg, SS, Adams, KK, Bade, KK, Krishna, GG, Benn, BB, Canfield, MM, Vetri Villalan, SS, Stewart, TT, Slebos, DD, Ten Hacken, NN, Klooster, KK, Hartman, JJ, Augustijn, SS. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (LIBERATE). Am. J. Respir. Crit. Care Med., 2018 May 23;198(9). PMID 29787288.

8. *Kemp, SS, Slebos, DD, Kirk, AA, Kornaszewska, MM, Carron, KK, Ek, LL, Broman, GG, Hillerdal, GG, Mal, HH, Pison, CC, Briault, AA, Downer, NN, Darwiche, KK, Rao, JJ, Hübner, RR, Ruwwe-Glosenkamp, CC, Trosini-Desert, VV, Eberhardt, RR, Herth, FF, Derom, EE, Malfait, TT, Shah, PP, Garner, JJ, Ten Hacken, NN, Fallouh, HH, Leroy, SS, Marquette, CC. A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (TRANSFORM). Am. J. Respir. Crit. Care Med., 2017 Sep 9;196(12). PMID 28885054.*
9. *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):1334-1342. PMID 22282552.*
10. *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):1066-1073. PMID 26116485.*
11. *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):1233-1244. PMID 20860505.*
12. *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):288-297. PMID 25321447.*
13. *Li, SS, Wang, GG, Wang, CC, Gao, XX, Jin, FF, Yang, HH, Han, BB, Zhou, RR, Chen, CC, Chen, LL, Bai, CC, Shen, HH, Herth, FF, Zhong, NN. The REACH Trial: A Randomized Controlled Trial Assessing the Safety and Effectiveness of the Spiration® Valve System in the Treatment of Severe Emphysema. Respiration, 2018 Dec 17;1-12:1-12. PMID 30554211.*
14. *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 17, 2020.*

15. *Du Rand IA, Barber PV, Goldring J, et al. Summary of the British Thoracic Society guidelines for advanced diagnostic and therapeutic flexible bronchoscopy in adults. Thorax. Nov 2011;66(11):1014-1015. PMID 22003155.*
16. *National Institute for Health and Care Excellence. Endobronchial valve insertion to reduce lung volume in emphysema. Available at: https://www.nice.org.uk/guidance/IPG600/chapter/1-Recommendations. Accessed April 17, 2020.*
17. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.128, Bronchial Valves. June 2019.*

X. POLICY HISTORY

TOP

MP-1.122	**CAC 4/26/11** New Policy. Adopted BCBSA. Placement of endobronchial valves is considered investigational. Endobronchial valves were previously addressed in another CBC MP, Lung Reduction Procedures (Investigational).
	CAC 6/26/12 Consensus review; no changes, references updated.
	2013 Codes added 12/20/2013
	03/28/13 Admin code changes
	CAC 9/24/13 Consensus review. References updated, but no changes to the policy statements. FEP variation revised to refer to the FEP medical policy manual. Rationale and policy guidelines added.
	CAC 7/22/14 Consensus. No change to policy statements. References updated.
	CAC 7/21/15 Consensus review. Policy statement edited for clarification only. Reference and rationale update**.** Codes reviewed.
	CAC 7/26/16 Consensus review. No change to policy statement. Regulatory Status, Rationale and Reference sections updated. Coding reviewed, removed 31634, 31660, 31661
	Administrative Update 11/23/16 Variation reformatting.
	CAC 9/26/17 Consensus review. Policy title revised to "Bronchial Valves". No changes to the policy statements. Background, rationale and references updated. Coding reviewed.
	6/7/18 Consensus. No change to policy statements. References updated. Rationale condensed.
	4/8/19 Consensus. No change to policy statements. Background, summary of evidence and references reviewed.
	4/17/2020 Consensus review. Policy statement unchanged. Background, Rationale, and References updated. Coding reviewed.

Top

POLICY TITLE	BRONCHIAL VALVES
POLICY NUMBER	MP-1.122

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