

Endobronchial Valve Surgery

Policy ID:	HHO-DE-MP-1225
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	12/15/2021; 03/01/2023
Original Effective Date:	01/15/2022; 04/01/2023
Annual Approval Date:	12/28/2022
Last Revision Date:	12/22/2021; 12/28/2022
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary endobronchial valve surgery.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children (DHCP) and Diamond State Health Plan Plus members.

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.

PROCEDURES

A prior authorization is not required.

Endobronchial valves that are approved by the Food and Drug Administration (FDA) (i.e., the Spiration Valve System and Zephyr Valve System) may be considered medically necessary for the treatment of adult individuals

with hyperinflation related to severe or very severe emphysema in regions of the lung that have little to no collateral ventilation.

Endobronchial valves for any other indication is considered experimental/investigational, and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/INVESTIGATIONAL (E/I) services are not covered regardless of place of service.

Endobronchial Valve Surgery is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT 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)).

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES 31647, 31651, 31648, 31649, AND 31651

Codes						
J43.0	J43.1	J43.2	J43.8	J43.9	J44.0	J44.1
J44.9						

CLASSIFICATION OF SEVERITY OF AIRFLOW OBSTRUCTION

Stages of Airflow Limitation	Severity Grouping
<p>GOLD 1 (mild):</p> <ul style="list-style-type: none"> FEV1 ≥ 80% predicted 	<p>Group A: low risk</p> <p>0-1 exacerbation per year, not requiring hospitalization, fewer symptoms.</p>

<p>GOLD 1 (moderate):</p> <ul style="list-style-type: none"> • 50% \leqFEV1 <80% predicted 	<p>Group B: low risk 0-1 exacerbation per year, not requiring hospitalization, more symptoms.</p>
<p>GOLD 3 (severe):</p> <ul style="list-style-type: none"> • 30% \leqFEV1 <50% predicted 	<p>Group C: high risk \geq2 exacerbations per year, or one or more requiring hospitalization, fewer symptoms.</p>
<p>GOLD 3 (very severe):</p> <ul style="list-style-type: none"> • FEV1 <30% predicted 	<p>Group D: high risk \geq2 exacerbations per year, or one or more requiring hospitalization, more symptoms.</p>

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

Reference

Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2020 Global Strategy for Prevention, Diagnosis, and Management of COPD. 2020.

van Agteren JE, Hnin K, Grosser D, et al. Bronchoscopic lung volume reduction procedures for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev.* 2017;2:CD012158.

Criner, G, 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.* 2018;198(9).

Dransfield MT, Garner JL, Bhatt SP, et al. Effect of zephyr endobronchial valves on dyspnea, activity levels and quality of life at one year. *Ann Am Thorac Soc.* 2020.

Kemp, S, Slebos, D, Kirk, A, et al. A multicenter randomized controlled trial of zephyr endobronchial valve treatment in heterogeneous emphysema (TRANSFORM). *Am J Respir Crit Care Med.* 2017;196(12).

Valipour, A, Slebos, D, Herth, F, et al. Endobronchial valve therapy in patients with homogeneous emphysema. Results from the IMPACT study. *Am J Respir Crit Care Med.* 2016;194(9).

van Geffen, W, Slebos, D, Herth, F, et al. Surgical and endoscopic interventions that reduce lung volume for emphysema: A systemic review and meta-analysis. *Lancet Respir Med.* 2019;7(4).

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.* 2019; 98(3):268-278.

Li, S, Wang, G, Wang, C, et al. 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;1-12:1-12.

Criner GJ, Delage A, Voelker K, et al. Improving lung function in severe heterogeneous emphysema with the spiration valve system (EMPROVE). A multicenter, open label randomized controlled clinical trial. *Am J Respir Crit Care Med.* 2019; 200(11): 1354-1362.

U.S. Food & Drug Administration. Spiration Valve System. Summary of Safety and Effectiveness Data.

U.S. Food & Drug Administration. Zephyr Valve System. Summary of Safety and Effectiveness Data.

Hayes Inc. Hayes Medical Technology Directory. Comparative effectiveness review of bronchoscopically placed coils or valves for lung emphysema: A review of reviews. Lansdale, Pa: Hayes, Inc; 02/25/2019.

Hayes Inc. Hayes Evidence Analysis Research Brief. Bronchoscopic removal of endobronchial valves in patients with persistent air leaks. Lansdale, Pa: Hayes, Inc; 09/25/2019.

Hartman JE, Klooster K, Ten Hacken NHT, van Dijk M, Slebos DJ. Patient satisfaction and attainment of patient-specific goals after endobronchial valve treatment. *Ann Am Thorac Soc.* 2021;18(1):68-74.

Klooster K, Slebos DJ. Endobronchial valves for the treatment of advanced emphysema. *Chest.* 2021;159(5):1833-1842.

Jarad N. Clinical review: Endobronchial valve treatment for emphysema. *Chron Respir Dis.* 2016;13(2):173-88.

POLICY UPDATE HISTORY

12/21/2021	Approved in Medical Policy Committee
01/2022	Approved in QI/UM
12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM