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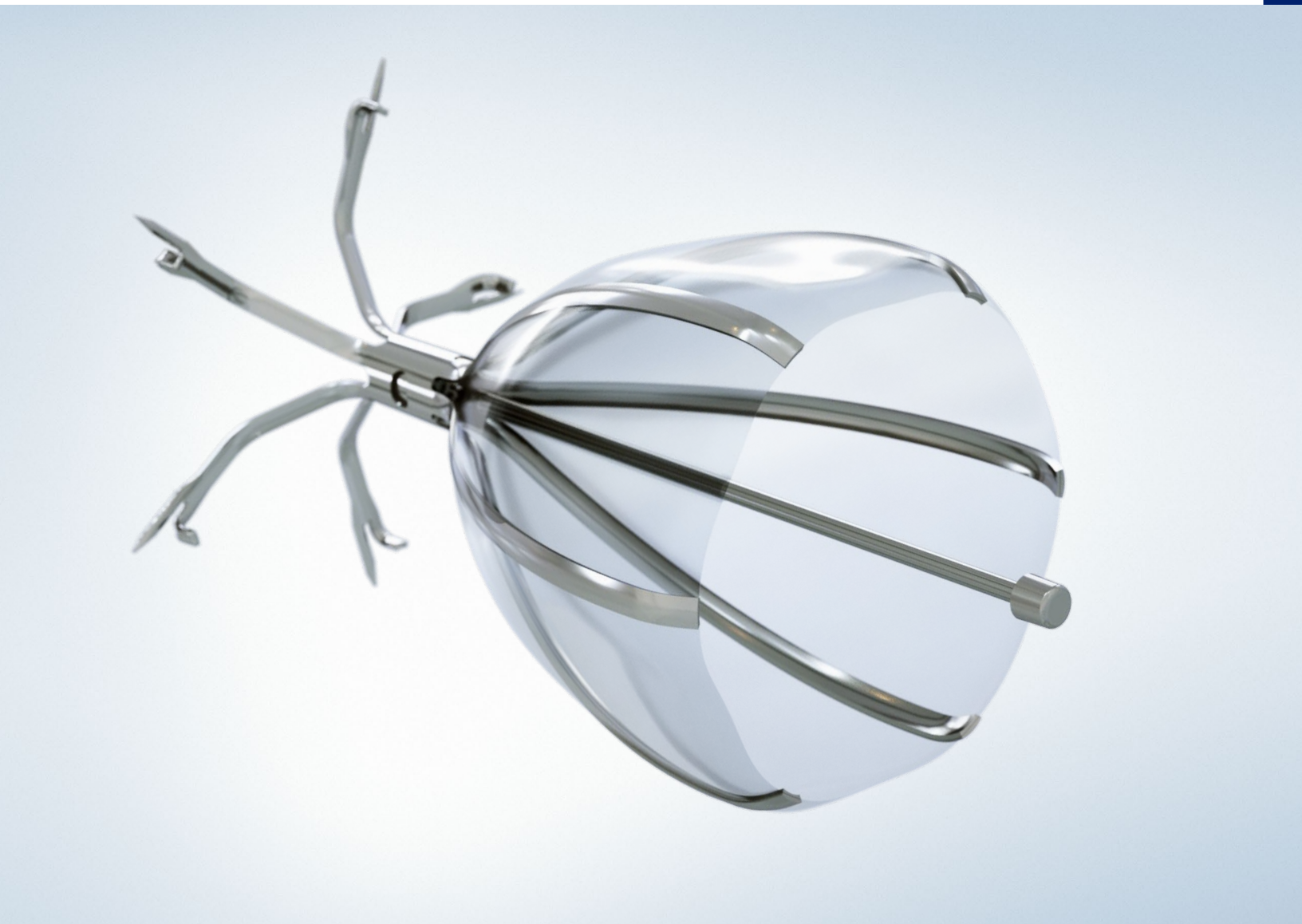
2022 Reimbursement Guide

Spiration™ Valve System for Use in Emphysema



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Introduction

Important Notice to Readers: This document is intended to help physicians, hospitals and ambulatory surgery centers, better understand coding, billing, coverage policies and reimbursement methodologies for endobronchial valve procedures that involve Olympus bronchoscopy equipment.

The information presented here is for illustrative purposes only and does not constitute reimbursement or legal advice. The reimbursement information provided by Olympus America Inc. and/or its direct or indirect (through one or more intermediaries) parent companies, affiliates or subsidiaries (collectively, the "Olympus Group") is gathered from third-party sources and is subject to change without notice. Reimbursement rules vary widely by insurer so you should understand and comply with any specific rules that may be set by the patient's insurer. You must also understand and comply with Medicare's complex rules. It is the provider's sole responsibility to determine medical necessity and in turn identify the appropriate codes, charges, and modifiers for services rendered to submit accurate claims. It is the provider's sole responsibility to determine medical necessity and to in turn identify which CPT codes to report and to submit accurate claims. You should always consult with your local payers regarding reimbursement matters. Under no circumstances shall the Olympus Group or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages (whether direct, indirect, special, incidental, consequential or otherwise) that may arise from or be incurred in connection with this information or any use thereof.

Coding recommendations, coverage policies, and reimbursement rates and methodologies vary by payer and are updated frequently. Providers should review applicable payer guidelines and instructions to ensure that billing practices comply with the payer's requirements and contact the payer if they have any questions.

The American Medical Association (AMA) is responsible for development and maintenance of Current Procedural Terminology (CPT®) codes. Providers should check the complete AMA CPT reference manual and/or another authoritative source for a complete listing of all CPT codes and their descriptors. It is the provider's responsibility to report the code(s) that accurately describes the procedure(s) furnished and the patient's diagnosis. Please note that the presence of a code, or billing a particular code, is not a guarantee of payment. Reimbursement will vary for each provider based on a number of factors, including the payer, site of service, geographic location and contractual terms.

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Indication for Use

The Spiration Valves are 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 collateral ventilation.

Caution

- **Contraindications:** Patient is not an appropriate candidate for, or unable to tolerate flexible bronchoscopy procedures. Patient with known or suspected sensitivity or allergy to nickel or latex. Patients with evidence of active pulmonary infection. Patients who have not quit smoking. Patients with large bullae encompassing greater than 30% of either lung. Patients with diffuse homogenous emphysema.
- **General Warnings:** The safety and effectiveness of the Spiration Valve System have not been studied in patients with prior major lung or chest surgery, Lung Volume Reduction Surgery (LVRS), transplant, median sternotomy or thoracotomy, known cardiac history of myocardial infarction or congestive heart failure, implanted endobronchial valve currently treating a prolonged air leak.
- **General Precautions:** Do not use the Spiration Valve System for other than its intended use. The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis. Only use a bronchoscope with a working channel of 2.6 mm or larger. Valve placement should be done only after airway evaluation and sizing with the balloon catheter and Airway Sizing Kit (see Instructions for Use, Airway Sizing Kit). Valve placement and removal must be done under bronchoscopic observation with visualization of the target airway. Do not allow lubricants to contact the catheter, loader, or valve. Once a valve has been loaded and/or deployed, do not attempt to reuse or re-deploy the valve. The valve is not designed to be repositioned after it is deployed from the catheter. If the position of the deployed valve is not optimal or appropriate, the valve should be removed and discarded. Do not remove the valve from the cartridge. Do not reuse the catheter and loader for more than one patient procedure. The catheter and loader are not designed to be re-cleaned, reprocessed, or re-sterilized. Do not deploy more than ten valves using the catheter and loader. If more than ten valve deployments are needed, a new catheter and loader must be opened and used.
- **Potential Adverse Effects:** Potential complications that may be associated with bronchoscopy and/or valve placement include, but are not limited to, the following: altered arterial blood gas, anesthesia complications, arrhythmia, atelectasis, bronchial injury, bronchitis, bronchospasm, chest pain, Chronic Obstructive Pulmonary Disease (COPD) exacerbation, death, dyspnea, empyema/lung abscess, hemoptysis (or bleeding), hemothorax, hypoxemia, Iatrogenic injuries, infection, migration of a valve out of the lung or within the lung, myocardial infarction, persistent cough, pneumothorax, pneumonia, respiratory failure, sore throat, thoracic pain, tissue hyperplasia or other reaction at valve site, valve fracture, vocal cord injury, wheezing and other procedure-related complications.

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Spiration Valve Procedure Overview For Emphysema

The current standard of care for patients with advanced COPD and/or emphysema is medical management. For patients where medication alone is ineffective, bronchoscopic lung volume reduction (BLVR) using endobronchial valves (EBV) is an alternative, minimally invasive approach.[1] Spiration Valves are one-way endobronchial valves placed in the airway via bronchoscopy. Once in place the valves are designed to occlude air from entering diseased areas of the lung, which reduces hyperinflation and allows the healthier lung to function better.

Inpatient Hospital Coding and Reimbursement

The Centers for Medicare & Medicaid Services (CMS) assigns discharges to Medicare Severity Diagnosis Related Groups (MS-DRGs) that determine inpatient reimbursement. Inpatient MS-DRG assignment and reimbursement is determined by ICD-10-PCS procedure code selection and ICD-10-CM primary and secondary diagnosis code related to the inpatient admission.

ICD-10-PCS Endobronchial Valve Procedure Codes

Hospitals use ICD-10-PCS procedure codes to describe procedures performed on inpatients. The table below identifies potential ICD-10-PCS procedure codes that may be used to describe the insertion and removal of the endobronchial valve(s). Hospitals are responsible for accurately selecting ICD-10-PCS procedure codes to describe the procedures performed during an inpatient stay.

The ICD-10-PCS procedure codes listed in this table are not intended to be an exhaustive list of all possible hospital procedure codes.

Potential ICD-10-PCS Procedure Codes for Spiration Valve System	
ICD-10-PCS Code	**ICD-10-PCS Description**
Valve Placement	
0BH38GZ	Insertion of Endobronchial Valve into Right Main Bronchus, Via Natural or Artificial Opening Endoscopic
0BH48GZ	Insertion of Endobronchial Valve into Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH58GZ	Insertion of Endobronchial Valve into Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH68GZ	Insertion of Endobronchial Valve into Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH78GZ	Insertion of Endobronchial Valve into Left Main Bronchus, Via Natural or Artificial Opening Endoscopic
0BH88GZ	Insertion of Endobronchial Valve into Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH98GZ	Insertion of Endobronchial Valve into Lingula Bronchus, Via Natural or Artificial Opening Endoscopic
0BHB8GZ	Insertion of Endobronchial Valve into Left Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
Valve Removal	
0WPQ8YZ	Removal of Other Device from Respiratory Tract, Via Natural or Artificial Opening Endoscopic

[1] 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. 2019;200(11):1354-1362.

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ICD-10-CM Diagnosis Codes

The table below identifies a potential list of ICD-10-CM primary diagnosis codes that may be used for emphysema. Hospitals and physicians should check with payers for clinical application of diagnosis codes for payment and coverage. Applicability and usage of these codes may vary per case.

The ICD-10-CM diagnosis codes listed in this table are not intended to be an exhaustive list of all possible diagnosis codes.

Potential ICD-10-CM Diagnosis Codes for Emphysema	
ICD-10-CM Code	**ICD-10-CM 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
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified

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Medicare Severity Diagnosis Related Groups (MS-DRGs)

The MS-DRG assignment will be influenced by the primary and secondary diagnosis codes reported for the stay along with other procedures that may be performed. Medicare will adjust reimbursement according to case severity which for many MS-DRGs consist of a family of 3 codes pertaining to the level of complication or comorbitities seen during the inpatient stay. The secondary diagnosis codes are used to make the determination of severity.

CMS has designated the EBV insertion procedure codes as affecting assignment to surgical MS-DRGs 163, 164 and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively).[1]

Below is the 2022 Medicare national inpatient reimbursement amount for MS-DRGs 163-165.

Medicare Inpatient Hospital Reimbursement		
MS-DRG	**MS-DRG Title**	**Inpatient Allowed Amount**
163	MAJOR CHEST PROCEDURES W MCC	$33,016
164	MAJOR CHEST PROCEDURES W CC	$17,512
165	MAJOR CHEST PROCEDURES W/O CC/MCC	$12,639

Note: Specific crosswalks may vary from the Centers for Medicare & Medicaid Services' General Equivalency Mappings
Inpatient payment amounts effective 10/1/2021 through 9/30/2022. MS DRG payment calculated with an average hospital base rate of $6594.31. Base rate of $6594.31 includes the national adjusted operating standardized amounts, labor 67.6% share and 32.4% non-labor share, for hospitals submitting quality and EHR data plus capital adjustment amounts.
Represents National Average Medicare Fees (Without Geographic Adjustment) Last Updated December 2021.

Sources: Inpatient Hospital: CMS-1752-F, Table 1A, 1D, and published 2021-8-13 Effective October 1,2021 through 09/30/2022.

[1] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the LongTerm Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals, 84 Fed. Reg. 42144 (August 16, 2019)

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Physician and Outpatient Hospital Coding and Reimbursement

CPT® Coding Overview

There are four Category I CPT codes to report bronchoscopy services for insertion and removal of bronchial valve(s) in CPT 2022 Professional Edition. The codes consist of a 2-code series for insertion (initial and each additional lobe), and a 2-code series for removal (initial and each additional lobe).

The Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed within or removed from a single lobe. Physicians should consider all available coding options and select the appropriate CPT code based on the procedure(s) performed.

Below are the coding descriptions for the insertion and removal of bronchial valves.

2022 Medicare Physician and Outpatient Hospital Reimbursement

CPT Codes	CPT Description	Physician Allowed Amount for Hospital/ASC	Hospital Outpatient Allowed Amount
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	$209	$5,947*
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])	$77	**
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	$200	$3,164*
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)	$68	$1,528

Represents National Average Medicare Fees Without Geographic Adjustment. Updated January 2022. Rates effective January 1, 2022 through December 31, 2022.

Sources:

- CPT & Description: Copyright 2021 American Medical Association. All rights reserved. Applicable FARS/DFARS apply to government use.
- Medicare Physician Fee Schedule: CMS-1734-F, addendum B published November 19, 2021. Physician payment amounts based on $34.6062 conversion factor effective 01/01/2022 through 12/31/2022. Physician Fee Schedule Procedures and Facility Payments may be subject to Medicare's Multiple Procedure Reduction Rules.
- Hospital Outpatient Fee Schedule: CMS-1751-FC, addendum B released November 2, 2021, effective 01/01/2022 through 12/31/2022.

* J1 code status Outpatient Hospital C-APC procedure is a comprehensive APC limiting payment for other procedures performed that day.

**Payment is packaged into the payment for 31647.

Frequently Asked Questions

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- **Will payers cover this procedure for emphysema patients?**

  Coverage will vary by insurer as new procedure coverage policies for emphysema develop. Absence of a formal coverage policy does not mean the technology or procedure is not covered. In the absence of a formal coverage policy, payers may provide coverage for services that are medically reasonable and necessary on a case-by-case basis. It is always a best practice to contact the insurance companies and determine patient benefits and coverage for a particular new technology or procedure.

  A sample medical necessity letter is available to assist you in making the case to the payer as to why the procedure was medically necessary for an individual patient.

- **Are prior authorizations required for the Spiration Valve System?**

  Under Medicare, prior authorizations are not required for any procedure. However, your local Medicare contractor may have specific processes that require submission of materials before a case is performed and billed to your local Medicare contractor.

  Commercial payers vary in their requirements for prior authorization for the Spiration Valve System. The provider should contact the patient's payer prior to performing any procedure that may require prior authorization.

- **How does the patient length of stay influence consideration of whether bronchoscopic lung volume reduction is designated as an inpatient hospital procedure?**

  Medicare and other payers require that the patient stay in the hospital greater than 48 hours to be considered an inpatient stay. Case specific circumstances (e.g. need for monitoring) will assist the physician in determining how long the patient needs to stay in the hospital, and whether the EBV insertion is designated as an inpatient or outpatient hospital procedure. It is important if the physician deems the patient needs to stay in the hospital greater than 48 hours that they document the reason why this clinical decision was made.

- **The CPT code 31647 descriptor refers to air leaks. Can I use this code for patients treated with valves for severe emphysema?**

  While CPT 31647 includes language regarding air leaks and airway isolation, it also includes airway sizing and insertion which are part of the SVS procedure for emphysema and therefore could be considered relevant. Please contact Reimbursement Support at (877) 205-1532 or by email olympusunite@priahealthcare.com, or contact your Local Area Coverage. We can provide you information from the American Thoracic Society (ATS) that provides guidance on the use of this code for emphysema.

- **What are the CPT® codes for bronchial valve insertion and/or removal?**

  There are four Category I CPT codes to report bronchoscopy services for the insertion and removal of bronchial valve(s). The codes consist of a 2-code series for insertion procedures (initial and each additional lobe) and a 2-code series for removal procedures (initial and each additional lobe). These Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed or removed from a single lobe.

Frequently Asked Questions

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- **Can multiple CPT codes be reported when more than one valve is inserted or removed from a single lobe?**

  Endobronchial valve insertion and removal CPT codes are intended to be billed only once per lobe.

- **Does HCPCS code (or C code) 1889 (Implantable/insertable device not otherwise classified) apply to the valve implanted for patients with emphysema?**

  Medicare guidance has determined that a device can be considered implantable if it is for single patient use. Implantable devices are required to remain in the patient post discharge for a period of 30 days. In most cases, the valve will remain in the patient for an extended duration. Depending on the intent of this procedure, the physician may determine, based on their clinical judgment, if the case fits the requirement for classifying this device as an implantable device.

Olympus Reimbursement Resources

Reimbursement Services and Programs

OLYMPUS UNITE for Spiration™ Valve System

Olympus has designated services and programs available to assist you with all of your reimbursement questions and needs related to the Spiration Valve System.

Contact Information:

Hours: 8:30 am – 5:00 pm Eastern Standard Time

Phone: 877-205-1532

Email: olympusunite@priahealthcare.com

Need Basic Reimbursement Information?

Feel free to call or email us and our trained staff can assist you with questions on billing, coding, and reimbursement for the Spiration Valve System.

Looking for More Support?

Experienced coding experts are available to help providers navigate your case-specific denials and prior authorizations. Our experts can assist with communication and paperwork between your payers, and then update you on case-specific decisions through a secured provider portal.

The following are the services that the reimbursement helpline offers:

- Assistance with the identification of coding for the Spiration Valve System
- Provision of additional details relating to medical documentation
- Review of payer explanation for denied prior authorizations/claims or underpaid claims
- Review of coding error related denials and guidance on how to resubmit or appeal the claim

If you are interested, please contact the OLYMPUS UNITE for Spiration Valve System (information listed above) to learn more about this service.

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For more information, contact your Olympus
sales representative, or call 800-848-9024.
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