pulmonX®

PULMONX® ZEPHYR® VALVE SYSTEM

AS OF JANUARY 1, 2020

This brochure describes a new procedure for treating severe emphysema in adults.
Caution: Federal law restricts this device to sale by or on the order of a physician.

zephyr® valve

INTRODUCTION

The reimbursement information provided in this guide is gathered from third-party sources and is subject to change without notice because of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement advice. Pulmonx® encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services that are rendered. Pulmonx recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

APPROVED INDICATION

The Pulmonx Zephyr® Endobronchial Valves are 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.

PLACE OF SERVICE

The Zephyr Valve procedure is performed as an inpatient procedure. To be a candidate, patients must have little to no collateral ventilation between the target and adjacent lobes.

A Stratx® Quantitative Lung CT Analysis, as part of the Zephyr Valve program, provides a non-invasive means to rule out patients with insufficient emphysema destruction and/or fissure completeness as this suggests too much collateral ventilation between lobes for the Zephyr Valve procedure to be effective. In some cases, Stratx can rule in a patient if the analysis shows 100% fissure completeness. However, to confirm little or no collateral ventilation and appropriateness for the Zephyr Valve procedure for otherwise eligible patients, a final assessment with the Chartis® System is typically performed. This physiological assessment of airflow is conducted through a bronchoscope. Therefore, the Chartis procedure is most often performed in the same setting/same procedure as placement of the Zephyr Valves. If after this assessment procedure the patient is determined to have collateral ventilation, no valves will be placed and the procedure will be terminated. In this case the patient will most often be discharged the same day and the place of service therefore considered outpatient. If the patient is determined not to have collateral ventilation following the Chartis assessment procedure, the Zephyr Valve procedure would be indicated, followed by a minimum three-day inpatient stay to monitor for possible side effects, the most common of which is pneumothorax.

POTENTIAL CPT® PROCEDURE CODES – FOR PHYSICIANS AND OUTPATIENT HOSPITAL PROVIDERS

Current Procedural Terminology (CPT) codes[1] are used to describe medical services and procedures provided by physicians; they are also used to report procedures performed in the outpatient facility setting. Physicians and outpatient hospital providers should consider the available coding options and select the appropriate CPT code based on the procedure(s) performed. Inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy.

Possible CPT Codes for Zephyr® Valve Insertion/Removal Procedures[2]

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
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)
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)

Possible CPT Codes for Chartis® Pulmonary Assessment Services

CODE	DESCRIPTION
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed (Do not report 31634 in conjunction with 31647, 31651 at the same session)

[1] CPT Copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.
[2] See ATS Coding and Billing Quarterly, December 2018, https://www.thoracic.org/about/newsroom/newsletters/coding-and-billing/resources/2018/cbq_december-18.pdf.

POTENTIAL ICD-10-PCS PROCEDURE CODES – FOR INPATIENT HOSPITAL PROVIDERS

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes[2] are used to describe procedures performed in the hospital inpatient setting. The table below identifies potential ICD-10-PCS procedure codes that may be used to describe the insertion and removal of the Zephyr® Valve(s). The ICD-10-PCS procedure codes listed in this table are not intended to be an exhaustive list of all possible hospital procedure codes. Hospitals are responsible for accurately selecting ICD-10-PCS procedure codes to describe the procedures performed during an inpatient stay.

Possible ICD-10 PCS Codes for Zephyr Valve Insertion/Removal Procedures[3]

CODE	DESCRIPTION
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
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
0WPQ8YZ	Removal of Other Device from Respiratory Tract, Via Natural or Artificial Opening Endoscopic

Possible ICD-10 PCS Code for Chartis® Pulmonary Assessment System Services

CODE	DESCRIPTION
4A0985Z	Measurement of Respiratory Flow, Via Natural or Artificial Opening Endoscopic

[3] ICD-10-PCS Official Guidelines for Coding and Reporting 2020, https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-ICD-10-PCS-Guidelines.pdf, See also, AHA Coding Clinic, Q3 2019.

POTENTIAL ICD-10 CM DIAGNOSIS CODES – FOR HOSPITALS AND PHYSICIANS

The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes[3] entered on physician and hospital claims convey information about the patient's condition to payers. Payers use this information to evaluate the episode of care and the appropriateness of the treatment the patient received. The table below identifies potential ICD-10-CM diagnosis codes for emphysema. Applicability and usage of these codes may vary per case. Hospitals and physicians also should check and verify current policies and requirements with the payer for any patient that will be treated with Zephyr® Valves.

Emphysema ICD-10-CM Diagnosis Codes[4]

CODE	DESCRIPTION
J43.0	Unilateral pulmonary emphysema
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J43.9	Emphysema, unspecified

[4] ICD-10-CM Reference Manual https://www.cdc.gov/nchs/icd/icd10cm.htm#FY%202019%20release%20of%20ICD-10-CM

HOSPITAL PAYMENT

The Zephyr® Valve procedure is performed as an inpatient procedure. To be a candidate, patients must have little to no collateral ventilation between the target and adjacent lobes. The Chartis® Pulmonary Assessment System is the final step to confirm that the patient has little to no collateral ventilation.

If after the assessment procedure with Chartis the patient is determined to have collateral ventilation, the patient may be discharged (no valves placed), and the place of service changed to hospital outpatient.

If the patient is determined not to have collateral ventilation, the Zephyr Valve procedure would be indicated to proceed, followed by a minimum three-night inpatient stay to monitor for possible side effects, the most common of which is pneumothorax.

Hospital Inpatient: Possible MS-DRG Assignment[5]

MS-DRG	DESCRIPTION	FY-2020 MEDICARE NATIONAL AVERAGE
163	Major Chest Procedures with MCC	$30,035
164	Major Chest Procedures with CC	$15,684
165	Major Chest Procedures without CC/MCC	$11,310

Hospital Outpatient: Possible APC Assignment[6]

CPT CODE	DESCRIPTION	APC	CY-2020 MEDICARE NATIONAL AVERAGE
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed	5155	$5,440

[5] Based on ICD-10 procedure coding noted on page 4. Reference CMS FY2020 IPPS Final Rule. CMS-1716-F.

[6] CPT code 31634 may apply to cases where the Chartis Pulmonary Assessment System is performed using bronchoscopy with balloon occlusion, but Zephyr Valves are not implanted. Reference CMS CY2020 Hospital Outpatient Prospective Payment System Final Rule, CMS-1717, Addendum B.

PHYSICIAN PAYMENT

Physician Payment by CPT code[7]		
CODE	DESCRIPTION	CY-2020 MEDICARE NATIONAL AVERAGE
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed	$199
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	$219
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	$208
+31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s)	$70
+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	$77

[7] Reference CMS CY2020 Physician Fee Schedule, Final Rule. CMS-1715-F

COVERAGE

Zephyr® Valves are Food and Drug Administration (FDA) approved. Providers should contact their individual payers prior to performing the Zephyr Valve procedure for information on coverage.

> An FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.
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> *8.7.2013, Federal Register, Vol. 78, No. 152, page 48165*

Under Medicare, the applicable test is whether the item or service is reasonable and necessary for the diagnosis or treatment of an illness or injury. Other payers assess coverage under a similar standard, though the terminology may be different (e.g., medically necessary).

Although not required, Medicare may develop national or local coverage policies specific to the procedure or technology. Currently, there is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for the Zephyr Valve procedure, but it is the responsibility of the provider to confirm current Medicare policies prior to administering the service to Medicare beneficiaries. When no policy exists, Medicare coverage determinations can be based on Medicare's "reasonable and necessary" requirement.

Under Medicare, a service is considered reasonable and necessary if it is:

- Safe and effective
- Not experimental or investigational
- Appropriate, including the duration and frequency that's considered appropriate for the item or service, in terms of whether it's:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

  CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.1

Other payers take similar considerations into account when assessing coverage of an item or service. All payers will look to published clinical literature when assessing coverage.

Traditional Medicare does not require or allow prior authorization or prior approval for procedures. However, Medicare Advantage plans are managed by commercial payers. Those payers may require prior authorization for Medicare Advantage patients.

Pulmonx® recommends pre-authorization of benefits for Zephyr® Valves with third-party payers that will allow it. Pulmonx offers support for patients, working with providers, through the pre-authorization process, in instances where consistent formal coverage has yet to be established. Customers using Zephyr Valves can contact Pulmonx Reimbursement Support at ReimbursementSupport@pulmonx.com, or 1.866.454.3006, for pre-authorization and appeal support for their patients.

Pulmonx Corporation provides this reimbursement guide for informational purposes only. This guide is not an affirmative instruction as to which codes and modifiers to use for a particular service or item. The coding, coverag, and payment information contained herein is gathered from various resources and is subject to change without notice.

It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Pulmonx recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Brief Statement: The Pulmonx Zephyr® Endobronchial Valves are 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. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Patients with evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking; Patients with large bullae encompassing greater than 30% of either lung. Use is restricted to a trained physician. Prior to use, please reference the Zephyr EBV System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Brief Statement: The Chartis® System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

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PAR104EN_E – January 2020 Coding Guide