

n05666

## Endobronchial Valves for the Treatment of Severe Emphysema

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### *Values*

Accountability • Integrity • Service Excellence • Innovation • Collaboration

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#### Abstract Purpose:

This policy provides guidance for the utilization management team of Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC (NHP/NHIC/NHAS/NH TPA) with review of requests for the use of The Zephyr® Endobronchial Valve System for the treatment of severe emphysema.

#### Policy Detail:

Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description, or Individual and Family Policy to determine eligibility and coverage because employer group and government contracts may vary. Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services LLC follows Medicare's National/Local (Wisconsin area) Coverage Determinations for its Medicare Advantage membership.

##### I. Description

- A. The Zephyr® Endobronchial Valve System is used for treating patients with severe emphysema. Endobronchial valves (EBV) have been proposed as a less invasive alternative to lung volume reduction surgery (LVRS) in emphysema, where damaged tissue is surgically removed to make the lungs smaller allowing them to function better.
- B. During the endobronchial valve placement procedure, a bronchoscope is inserted through the mouth, passing through the larynx and trachea into the bronchial pathways. Once the scope reaches the damaged portion of the lung, a one-way valve is implanted to prevent airflow into the area while allowing trapped air and fluids to escape. Based on the condition of the individual's lungs, multiple valves may be implanted.

##### II. Medical Indications

- A. Endobronchial valve placement for the treatment of severe emphysema is considered medically necessary when all of the following criteria are met:
  - 1. Age 40 to 75 years; **AND**
  - 2. BMI less than 35 kg/m<sup>2</sup>; **AND**
  - 3. No hospitalizations as a result of a COPD exacerbation within the past 12 weeks and managed with less than 20mg Prednisone (or equivalent) daily; **AND**
  - 4. The member has been nonsmoking for four (4) months prior to initial evaluation; **AND**

5. A supervised pulmonary rehabilitation program was completed less than or equal to six (6) months prior to initial evaluation; **AND**
  6. The member has received an influenza vaccination as currently available and pneumococcal vaccination; **AND**
  7. FEV1 between 15%-45% of predicted value at initial evaluation; **AND**
  8. Little or no collateral ventilation (CV) as determined using the Chartis system; **AND**
  9. The device(s) used must be approved by the FDA and used according to FDA labeling; **AND**
  10. Absence of contradictions listed in the Coverage Limitations section
- III. Coverage
- A. Endobronchial valve placement for the treatment of severe emphysema is a covered benefit when deemed medically necessary per the criteria listed above.
  - B. In the absence of a CMS National or Local Coverage Determination, NHP/NHIC/NHAS follows the criteria within the policy for application to its Medicare Advantage membership.
- IV. Limitations/Exclusions
- A. Individuals who are unable to tolerate bronchoscopic procedures; **OR**
  - B. Known allergy to device materials (nitinol, nickel, titanium, or silicone); **OR**
  - C. Myocardial infarction within 90 days of initial evaluation or diagnosis of congestive heart failure; **OR**
  - D. Two (2) or more COPD exacerbations or two (2) or more episodes of pneumonia within the previous 90 days; **OR**
  - E. Prior lung transplant, lung volume reduction surgery (LVRS), bullectomy or lobectomy; **OR**
  - F. Active smokers
  - G. Unable to safely discontinue anticoagulants or platelet activity inhibitors for seven (7) days; **OR**
  - H. Uncontrolled pulmonary hypertension (systolic pulmonary arterial pressure greater than 45 mm Hg) or evidence or history of cor pulmonale as determined by recent echocardiogram (completed within the last 90 days).
- V. References
- A. Ferguson, G.T. (updated through 2023, November 17,) Management of refractory chronic obstructive pulmonary disease. UpToDate. [www.uptodate.com](http://www.uptodate.com) Accessed 01/22/2025
  - B. Machuzak, M.S (updated through 2023, June 9,) Bronchoscopic treatment of emphysema. UpToDate. [www.uptodate.com](http://www.uptodate.com) Accessed 01/05/2024.
  - C. MCG, 29th Edition Bronchoscopy, Diagnostic and Interventional ACG: A-0244
  - D. MCG, 29th Edition- Thoracic surgery or procedure GRG: SG-TS (ISC GRG)
  - E. US Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Zephyr endobronchial valve system. Notice of FDA approval June 29, 2018. Accessed January 22, 2025.

### Regulatory Citations:

UM2

### Related Documents:

CPT Codes:

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])
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed. (Chartis Pulmonary Assessment)
	*CPT codes are subject to change as codes are retired or new ones developed. Code list may not be all inclusive.

**Disclaimer:**

Contract language as well as state and federal laws take precedence over any medical policy. Network Health coverage documents (i.e., Certificate of Coverage, Evidence of Coverage, Summary Plan Descriptions) outline contractual terms of the applicable benefit plan for each line of business and will be considered first in determining eligibility. Not all Network Health coverage documents are the same. Coverage may differ. Our Medicare membership follows applicable Centers for Medicare and Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Please refer to the CMS website at [www.cms.gov](http://www.cms.gov).

Network Health reserves the right to review and update our medical policies on occasion as medical technologies are constantly evolving. The documentation of any brand name of a test, product and/or procedure in a medical policy is in no way an endorsement of that product; it is for reference only.

Network Health's medical policies are for guidance and not intended to prevent the judgement of the reviewing medical director(s) nor dictate to health care providers how to practice medicine.

<b>Origination Date:</b> 01/11/2020	<b>Approval Date:</b> 2/20/2025	<b>Next Review Date:</b> 2/20/2026
<b>Regulatory Body:</b> NCQA	<b>Approving Committee:</b> Utilization Management Committee	
<b>Department of Ownership:</b> Utilization Management		<b>Revision Number:</b> 6
<b>Revision Reason:</b> 02/19/2020 – New Policy 02/17/2021-minor grammatical & formatting updates, CPT codes & disclaimer added, references updated, stable on Prednisone and current vaccinations better defined. 02/17/2022 - minor grammatical and formatting updates, disclaimer added, references updated Approved by Medical Policy Committee on 02/17/2022 3/16/2023 – minor grammatical and formatting changes, references updated. Approved at Medical Policy Committee on 3/16/2023. 2/15/2024- annual review. References updated. CPT/HCPCS codes reviewed and updated. 02/20/2025-annual review, References updated. CPT/HCPCS codes reviewed and updated, added NH TPA as a covered LOB.		