

n05666

Endobronchial Valves for the Treatment of Severe Emphysema

Values

Accountability • Integrity • Service Excellence • Innovation • Collaboration

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) 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/m²; **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 Accessed 01/05/2024
 - B. Machuzak, M.S (updated through 2023, June 9,) Bronchoscopic treatment of emphysema. UpToDate. www.uptodate.com Accessed 01/05/2024.
 - C. MCG, 27th Edition Bronchoscopy, Diagnostic and Interventional ACG: A-0244
 - D. MCG, 27th 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 5, 2024.

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 (eg, 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.

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.

Origination Date: 01/11/2020	Approval Date: 2/15/2024	Next Review Date: 2/15/2025
Regulatory Body: NCQA	Approving Committee: Medical Policy Committee	Policy Entity: NHAS,NHIC,NHP
Policy Owner: Rachell Hall	Department of Ownership: Utilization Management	Revision Number: 5
Revision Reason: 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.

Meeting: Utilization Management Committee	Date: 2/15/2024
Title/Topic: Medical Policy – Endobronchial Valves for the Treatment of Severe Emphysema	Policy Number: n05666
Purpose: Annual Review	Outcome: Choose an item.
Line of Business: Commercial and Medicare	Effective Date: 2/15/2024

INTRODUCTION:

Includes definition of problem or opportunity. Provides background information on the topic. Describes current state. May also include prior state and/or factors that have changed. Includes operational definitions where key terms may have varied interpretation.

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.

This medical policy provides guidance for Utilization Management Coordinator Registered Nurses (UMC-RN) regarding determinations involving the medical necessity of endobronchial valve placement for the treatment of severe emphysema. This policy is due for annual review.

ACTION RECOMMENDED:

States recommendations in specific terms. Includes a summary of what should be accomplished, methods, and timetable (if applicable). Recommendations on implementation and follow-up plans may also be included.

Annual review has been conducted and the Endobronchial Valves for the Treatment of Severe Emphysema medical policy is presented for review and approval as written.

No changes were made to the intention or utilization guidance of this policy. Annual review was performed, a review and update of references was conducted, and CPT/HCPCS code verification and update was completed.

ANALYSIS/JUSTIFICATION:

Includes information relevant to the recommended action including information used in formulation the recommendations. Information will include reference to any existing Centers for Medicare & Medicaid Services (CMS) coverage determinations as well as any existing established vendor criteria. Information may include financial/cost data, service measures, projections or other key measures or process tools, recommendations from a clinical provider with expertise regarding the topic, and/or information from other widely used treatment guidelines or peer reviewed clinical literature.

Centers for Medicare & Medicaid Services (CMS) does not have a National Coverage Determination (NCD) or Local Coverage Determination (LCD) specific to Zephyr or endobronchial valves. CMS does have an NCD which addresses lung volume reduction surgery (LVRS), but NCD does not provide any reference or guidance surrounding the use of endobronchial valve to achieve lung volume reduction.

MCG 27th edition provides no specific guidelines for endobronchial valve surgery but does include a footnote under the Thoracic Surgery or Procedure GRG discussing bronchoscopic lung volume reduction achieved by endobronchial valve as well as lung volume reduction surgery. The footnote indicates a need for appropriate selection of patients for procedure but does not provide specific criteria to evaluate the medical necessity as applied to an individual patient.

Endobronchial valve lung volume reduction is supported for appropriately selected patients by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) and National Institute for Health and Care Excellence (NICE).

Analysis of competitor payor medical policy demonstrates similar medical policies developed for use in determining the medical necessity for endobronchial valve lung volume reduction surgery.

REFERENCES:

Includes detailed description regarding source(s) of information used for development of policy or recommendations via citation.

- Ferguson, G.T. (updated through 2023, November 17,) Management of refractory chronic obstructive pulmonary disease. UpToDate. www.uptodate.com Accessed 01/05/2024.
- Machuzak, M.S (updated through 2023, June 9,) Bronchoscopic treatment of emphysema. UpToDate. www.uptodate.com Accessed 01/05/2024.
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REVISION REASON:

Includes the date changes or updates were made and summary of changes applied.

2/15/2024- Annual review was completed. References were reviewed and updated. A CPT/HCPCS code review was conducted with updates made.

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