Priority Health

MEDICAL POLICY
No. 91472-R6

LUNG VOLUME REDUCTION (SURGICAL AND NON-SURGICAL)

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Date Of Origin: November 19, 2003

Status: Current

I. POLICY/CRITERIA

A. **Lung Volume Reduction Surgery (LVRS):** Priority Health considers LVRS medically necessary when ***all*** of the following are present:

1. Either of the following:
   a. Severe upper lobe emphysema; ***or***
   b. Severe non-upper lobe emphysema with low exercise capacity.
2. Pulmonary Rehabilitation as follows:
   a. Pre-operative: 6 - 10 week series of at least 16, and no more than 20, preoperative sessions each lasting a minimum of two hours.
   b. Post-operative: at least 6 and no more than 10 postoperative sessions each lasting a minimum of two hours, within 8 to 9 weeks of the LVRS.
   c. Specific components of the pulmonary rehabilitation program must include:
      - Comprehensive evaluation of medical, psychosocial and nutritional needs
      - Setting of goals for education and exercise training
      - Exercise training (lower extremity, flexibility, strengthening, and upper extremity)
      - Education about emphysema and medical treatments
      - Psychosocial counseling
      - Nutritional counseling
3. ***ALL*** of the following:
   a. Radiographic evidence of moderate to severe bilateral emphysema,
   b. Forced expiratory volume in one second (FEV_1) $\leq$ 45% predicted or $\geq$ 15% predicted if age $\geq$ 70 years)
   c. Non-smoking for at least 4 months
   d. Participation in pulmonary rehabilitation with the attainment of preset performance goals (e.g., ability to complete three minute unloaded pedaling in an exercise tolerance test).

4. ***NONE*** of the following:
   a. Previous LVRS or lobectomy,
   b. Patient is high risk. High-risk patient is defined as one with a forced expiratory volume in the first second (FEV_1) that is 20% or less of their predicted value and either homogeneous distribution of emphysema on CT scan or low carbon monoxide diffusing capacity (D_LCO) that is 20% or less of their predicted value.
   c. COPD conditions unsuitable for LVRS (e.g., bronchiectasis, chronic bronchitis, and CT evidence of diffuse emphysema judged unsuitable),
   d. Systemic disease or neoplasias expected to compromise survival during five-year period,
   e. Medical conditions or other circumstances make it likely that the patient will be unable to complete the pre- and postoperative pulmonary diagnostic and therapeutic program required for surgery
5. LVRS approach must be a bilateral excision of damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

B. **Bronchoscopic (non-surgical) lung volume reduction (BLVR) for Chronic Obstructive Lung Disease**:

Priority Health considers the implantation of FDA approved endobronchial valves (e.g., Zephyr® Endobronchial Valves (Pulmonx), Spiration (Olympus Respiratory, etc.), medically necessary only for the indication of emphysema, and only if the patient meets ***ALL*** of the listed selection criteria and exhibits ***NONE*** of the listed contraindications.

1. Patient Selection Criteria (patient must meet ***ALL***):
   a. Diagnosis of emphysema confirmed by CT
   b. Body Mass Index (BMI) < 35 kg/m^2
   c. Stable with ≤ 20 mg prednisone (or equivalent) daily
   d. Residual Volume (RV) ≥ 175% predicted (≥ 200% if homogeneous)
   e. Force Expiratory Volume in 1 second (FEV_1) between 15 and 45% predicted
   f. Total Lung Capacity (TLC) ≥ 100% predicted
   g. Diffusing Capacity for carbon monoxide (D_{LCO}) ≥ 20% predicted
   h. 6-minute walk distance (6MWD) 100-500 m (150-500 m if homogeneous)
   i. Not actively smoking (smoking cessation for at least 4 months leading up to procedure)
   j. Completed and submitted preliminary assessment of collateral ventilation within target lobe (as measured by Chartis® Assessment and/or StratX® Lung Analysis Platform; or SeleCT™ QCT analysis service)

2. Contraindications (patient must exhibit ***NONE***):
   a. Bronchoscopic procedures are contraindicated
   b. Evidence of active pulmonary infection
   c. Known allergies to Nitinol, Nickel, Titanium, or Silicone
   d. Current smoker
   e. Large bullae encompassing greater than 30% of either lung
   f. Less than 85% fissure integrity in the lobe intended to be treated as measured by quantitative CT fissure analysis or Chartis® Assessment.

C. **Exclusions:** Priority Health considers any of the following experimental, investigational, and/or unproven, and therefore not medically necessary, as there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management:

1. Endobronchial **coils** (including, but not limited to, the following: PneumRx (PneumRx Inc.))

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met***

and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee

IV. DESCRIPTION

Lung volume reduction surgery (LVRS) involves removal of bullae and nonfunctional lung tissue in patients with **chronic obstructive pulmonary disease (COPD)** due to emphysema. The objective of this procedure is to allow re-expansion of the remaining compressed lung, which in turn may allow the lung to inflate to a more normal capacity and to function more efficiently, and may reduce the size of the thoracic cavity to achieve a more optimal respiratory muscle action and ventilatory capacity.

There is some evidence from randomized trials that LVRS can produce significant improvements in pulmonary function, dyspnea, exercise capacity, and quality of life compared with medical therapy in selected patients with upper lobe pathology, and can reduce mortality in patients with upper lobe pathology and low exercise tolerance. However, LVRS can also increase mortality in certain patient populations, and there is a relatively high early mortality rate associated with the procedure. LVRS is palliative not curative.

Bronchoscopic lung volume reduction (BLVR) entails nonsurgical physical intervention with access from the nose or mouth to the lungs, targeting diseased tissue identified by imaging. Valves provide one-way flow that allow air to exit but not enter segments distal to where they are implanted, reducing air trapping. When valves are in place, expiration of air continues normally but air flow on inspiration is blocked, which is intended to cause the upper lobes to gradually lose volume and collapse.

Endobronchial valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with sever emphysema in regions of the lung that have little to no collateral ventilation (airflow between lobes through channels that bypass normal airways).

The **Chartis® System** is a proprietary pulmonary assessment tool that enables physicians to identify those patients likely to respond to the Pulmonx Zephyr valves with a high degree of confidence. The Chartis system provides precise flow and pressure readings for specific lobes in the lungs to assess collateral ventilation. Clinical studies outside of the US have shown that patients with low to no collateral ventilation respond best to Zephyr valve therapy.

StratX® is a cloud-based quantitative CT analysis service that supports Zephyr valve patient selection and treatment targeting by providing clinically validated information on emphysema destruction, fissure completeness and volume.

Olympus offers the **SeleCT™ QCT** analysis service to evaluate patient eligibility for treatment with the Spiration® Valve System. The SeleCT QCT analysis service analyzes previously taken CT images to quantify important measures of emphysema, including emphysema distribution (heterogeneity), the severity of lung tissue destruction and fissure integrity between the lobes of the lung (which has been shown to be a surrogate for collateral ventilation).

V. CODING INFORMATION

ICD-10 Codes that may support medical necessity*:*
J43.0 - J43.9 Emphysema

CPT/HCPCS 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])

32141 Thoracotomy; with resection-plication of bullae, includes any pleural procedure when performed

32491 Removal of lung, other than total pneumonectomy; excision-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, with or without any pleural procedure

32655 Thoracoscopy, surgical; with resection-plication of bullae, includes any pleural procedure when performed

32672 Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed

Billed by facilities under only:

G0302 Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services

G0303	Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services
G0304	Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services
G0305	Post discharge pulmonary surgery services after LVRS, minimum of 6 days of services

VI. REFERENCES

1. Criner GJ, 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 Vol 198, Iss 9, pp 1151–1164, Nov 1, 2018.
2. FDA. Zephyr® Endobronchial Valve System: Instructions for Use. Pulmonx Corporation.
3. Gompelmann D, et al. Long-term follow up after endoscopic valve therapy in patients with severe emphysema. Ther Adv Respir Dis 2019; 13: 1–11. DOI: 10.1177/1753466619866101.
4. Hayes Inc. Bronchoscopically Placed Coils or Valves for Lung Emphysema: A Review of Reviews. February 25, 2019. Annual Review January 19, 2022.
5. Hayes, Inc. Lung Volume Reduction Surgery for Chronic Obstructive Pulmonary Disease, December 2003 and Updated Search December 2005.
6. Hayes Inc. Zephyr Endobronchial Valve (Pulmonx) for Treatment of Emphysema. October 23, 2018.
7. Kemp SV, 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; 196 (12): 535–1543, Dec 15, 2017.
8. Li S, 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 2019; 97:416–427. DOI: 10.1159/000494327.
9. Lung Volume Reduction Surgery (Reduction Pneumoplasty). National Coverage Determination (NCD) 240.1. Centers for Medicare & Medicaid Services (CMS).
10. National Emphysema Treatment Trial Research Group. Cost Effectiveness of Lung-Volume-Reduction Surgery for Patients with Severe Emphysema. The New England Journal of Medicine, 348 (21); 2092-2102, May 22, 2003.
11. National Institute for Health and Care Excellence (NICE)Endobronchial valve insertion to reduce lung volume in emphysema. Interventional procedures guidance [IPG600].