I. Policy: Lung Volume Reduction Surgery

II. Purpose/Objective:
   To provide a policy of coverage regarding Lung Volume Reduction Surgery

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions
   1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
   2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
   3. Devised – the date the policy was implemented.
   4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
   5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

   a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
   c. in accordance with current standards of good medical treatment practiced by the general medical community.
   d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
   e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

   (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
   (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
   (iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Lung volume reduction surgery is a surgical treatment for severe emphysema. The surgical intent of lung volume reduction is to reduce airway obstruction by improving lung elastic recoil and by providing more effective diaphragmatic function by reducing lung hyperinflation. Lung volume reduction surgery is performed by excision of the affected lung tissue through an open thoracotomy or by video-assisted thoracoscopy.

The placement of small self-expanding 1-way valves into airways is a minimally invasive approach currently under investigation as an alternative to open LVRS. The implantable valves are deployed in diseased bronchial segments using a flexible fiber-optic bronchoscope inserted through the mouth or nose. The valves are designed to prevent incoming airflow from reaching over-inflated regions of the lung while permitting trapped gas to escape. In addition to isolating non-functional areas of the lungs, the valves have the potential to reduce hypoxemia and hypercarbia by directing airflow to areas where gas exchange is less impaired.

INDICATIONS:
REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION

Emphysema when all of the following criteria are met:

CRITERIA FOR ELIGIBILITY:
➢ All surgeries must be performed at a CMS approved Center of Excellence
➢ Member has severe predominantly upper lobe emphysema; OR
➢ Member has severe non-upper lobe emphysema with low base-line exercise capacity (defined as below 25 watts for women and below 40 watts for men); and

Satisfies all of the criteria outlined below:

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<tr>
<th>Assessment</th>
<th>Criteria</th>
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<tr>
<td>History /Physical Exam</td>
<td>Consistent with emphysema</td>
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<td>BMI less than or equal to 31.1 kg/m2 (men) or less than or equal to 32.3 kg/m2 (women)</td>
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<td>Stable with less than or equal to 20 mg prednisone (or equivalent) per day</td>
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<td>Radiographic</td>
<td>Evidence of bilateral emphysema with a High Resolution Tomography Scan.</td>
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<td>Pulmonary Function (pre-rehab)</td>
<td>Forced expiratory volume in one second (FEV1) less than or equal to 45% predicted (15% or greater predicted if age 70 years or more)</td>
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<td>Total lung capacity equal to or greater than 100% predicted post bronchodilator</td>
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<td>Residual volume 150% or greater predicted post bronchodilator</td>
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<td>Arterial Blood Gas (pre-rehab)</td>
<td>PCO2 60mmHg or less (55mmHg or less if 1 mile above sea level)</td>
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<td>PO2 45 mmHg or greater on room air (30 mmHg or greater if 1 mile above sea level)</td>
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<td>Cardiac</td>
<td>Approval for surgery by a cardiologist if any of the following are present:</td>
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<td>• Unstable angina</td>
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<td>• LVEF cannot be estimated from echocardiogram</td>
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<td>• LVEF 45% or less</td>
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<td>Assessment</td>
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| • Dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction  
• Arrhythmia (more than 5 PVC’s /minute; cardiac rhythm other than sinus; PVC on EKG at rest) | Approved for surgery by a pulmonary physician, thoracic surgeon and anesthesiologist post-rehabilitation |
| Surgical   | Post rehabilitation 6 minute walk of 140 meters or more; able to complete 3 minutes of unloaded pedaling in exercise tolerance test (pre and post rehab) |
| Exercise   | Plasma cotinine level of 13.7 ng/mL or less (or arterial carboxyhemoglobin of 2.5% or less if using nicotine products) |
| Smoking    | Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery |

**National Coverage Determination (NCD) for LUNG VOLUME REDUCTION Surgery (REDUCTION Pneumoplasty) (240.1)**

**NOTE:** Effective March 2, 2006 For member enrolled in the Gold product only, Medicare will consider LVRS reasonable and necessary only when services are performed on or after November 17, 2005 and performed at a facility that is:

- Certified by the Joint Commission on Accreditation of Healthcare Organizations (joint Commission) under the LVRS Disease Specific Care Certification Program; OR
- Approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial; OR
- Medicare-certified for lung or heart-lung transplantation.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at: [http://www.cms.hhs.gov/MedicareApprovedFacilitie/LVRS/list.asp](http://www.cms.hhs.gov/MedicareApprovedFacilitie/LVRS/list.asp)

**EXCLUSIONS:**
The Plan does not cover Laser bullectomy for emphysema or bronchoscopic lung volume reduction procedures (e.g., bronchial valve placement, biologic lung volume reduction, bronchopulmonary fenestration) because they are considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this procedure on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

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**CODING ASSOCIATED WITH LUNG VOLUME REDUCTION SURGERY:**
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

**CPT Codes:**
32124 thoracotomy, with open intrapleural pneumoyysis
32141 thoracotomy, with excision – plication of bullae, with or without any pleural procedure
thoracoscopy, surgical, with excision – plication of bullae, including any pleural procedure
Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed
unlisted procedure, lungs and pleura
Excision-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach with or without and pleural procedure
Plethysmography for determination of lung volumes and, when performed, airway resistance
Gas dilution or washout for determination of lung volumes and, when performed, distribution of ventilation and closing volumes
Pre-op service LVRS complete
Pre-op service 10-15 dos
Pre-op service 1-9 dos
Post op service LVRS

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Centers for Medicare and Medicaid Services. Pub. 100-03


ECRI Institute Forecast (online). Endobronchial valves for emphysema. April 06, 2010

Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of chronic obstructive pulmonary disease (COPD). Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); March 2013


This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/96

Revised: 1/98, 6/02, 6/03(definition, criteria, reference); 7/05 (update criteria); 11/06(Update Criteria); 12/10 (exclusion added), 12/11(updated criteria)

Reviewed: 11/07, 11/08, 11/09, 12/12, 12/13, 12/14; 12/15, 12/16, 11/17, 11/18, 10/19