Lung volume reduction surgery (LVRS) is proposed as a treatment option for patients with severe emphysema who have failed optimal medical management. The procedure involves the excision of diseased lung tissue and aims to reduce symptoms and improve quality of life.

Lung volume reduction is a surgical treatment for patients with severe emphysema involving the excision of peripheral emphysematous lung tissue, generally from both upper lobes. The precise mechanism of clinical improvement for patients undergoing lung reduction surgery has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of diseased lung. In addition to changes in chest wall and respiratory mechanics, the surgery is purported to correct ventilation perfusion mismatch and improve right ventricular filling.

Lung volume reduction surgery is intended to be palliative not curative. The procedure is designed to relieve dyspnea and improve functional capacity and quality of life. Patients continue to have severe emphysema, and most patients will show further progression of their disease over time. It is also hoped that LVRS may extend survival time.

II. Criteria/Guidelines

A. Bilateral excision of the damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery is covered (subject to Limitations/Exclusions and Administrative Guidelines) when all of the following requirements are met:
1. The patient satisfies all the criteria outlined below:
   a. History and physical examination
      i. Findings consistent with emphysema
      ii. Body Mass Index (BMI) < 31.1 kg/m$^2$ (men) or < 32.3 kg/m$^2$ (women)
      iii. Stable with ≤ 20 mg prednisone (or equivalent) per day
   b. Radiographic
      i. High-resolution computer tomography (HRCT) scan shows evidence of bilateral emphysema
   c. Pulmonary function (prerehabilitation)
      i. Forced expiratory volume in one second (FEV1) ≤ 45 percent predicted and > 15 percent if the patient is age 70 or older
      ii. Total lung capacity (TLC) ≥ 100 percent predicted postbronchodilator
      iii. Residual volume (RV) > 150 percent predicted postbronchodilator
   d. Arterial blood gas level (prerehabilitation)
      i. Partial pressure of carbon dioxide artery (PCO2) ≤ 60 mm/Hg (PCO2 ≤ 55 mm/Hg if one mile above sea level)
      ii. Partial pressure of oxygen artery (PO2) ≥ 45 mm/Hg on room air (PO2 ≥ 30 mm/Hg if one mile above sea level)
   e. Cardiac Assessment. Approval for surgery by cardiologist if any one of the following is present:
      i. Unstable angina;
      ii. Left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram;
      iii. LVEF < 45 percent;
      iv. Dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction;
      v. Arrhythmia (> 5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on electrocardiogram at rest)
   f. Surgical Assessment
      i. Approval for surgery postrehabilitation by pulmonary physician, thoracic surgeon, and anesthesiologist
   g. Exercise
      i. Postrehabilitation six minute walk of ≥ 140 m; able to complete three minute unloaded pedaling in exercise tolerance test (pre- and postrehabilitation)
   h. Consent
      i. Signed consents for screening and rehabilitation
   i. Smoking
      i. Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin < 2.5 percent if using nicotine products)
      ii. Nonsmoking for four months prior to initial interview and throughout evaluation for surgery
   j. Preoperative diagnostic and therapeutic program adherence
Lung Volume Reduction Surgery

i. Must complete assessment for and program of preoperative services in preparation for surgery

B. In addition, the patient must have:

1. Severe upper lobe predominant emphysema (as defined by radiologist's assessment of upper lobe predominance on CT scan), or
2. Severe non-upper lobe emphysema with low exercise capacity
   a. Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts for men after completion of the preoperative therapeutic program in preparation for LVRS.
   b. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing five or 10 watts/minute ramp on 30 percent oxygen after three minutes of unloaded pedaling.

C. LVRS when determined reasonable and necessary will be covered when performed at facilities that are:

1. Certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or
2. Approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT).
3. A list of Medicare approved facilities and their approval dates is listed on the CMS website:

- The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery.

- The program must include a six- to 10-week series of at least 16, and no more than 20, preoperative sessions each lasting a minimum of two hours. It must also include at least six, and no more than 10, postoperative sessions each lasting a minimum of two hours, within eight to nine weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

III. Limitations/Exclusions

A. LVRS is not covered in any of the following clinical circumstances:

1. The patient characteristics carry a high risk for perioperative morbidity and/or mortality.
2. The disease is unsuitable for LVRS.
3. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery (See Criteria II.D.)

4. The patient presents with FEV1 < 20 percent of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of < 20 percent of predicted value (high-risk group identified October 2001 by the NETT); or

5. The patient satisfies the criteria outlined in section II.A. but has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 watts for women and 40 watts for men (under the measurement conditions for cycle ergometry specified above).

B. All other indications for LVRS not otherwise specified remain noncovered.

C. HMSA-covered LVRS approaches are limited to bilateral excision of the damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

IV. Administrative Guidelines

A. Precertification is required for LVRS. To precertify, please complete HMSA's Precertification Request and mail or fax the form as indicated.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>32491</td>
<td>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</td>
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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0302</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services</td>
</tr>
<tr>
<td>G0303</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services</td>
</tr>
<tr>
<td>G0304</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, one to nine days of services</td>
</tr>
<tr>
<td>G0305</td>
<td>Post-discharge pulmonary surgery services after LVRS, minimum of six days of services</td>
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V. Scientific Background

This policy is based on the final results of the NETT. The trial reported the results of all 1,218 patients who underwent randomization. The primary outcomes included total, 30- and 90-day mortality and maximal exercise capacity. Secondary outcomes included pulmonary function, the distance walked in six minutes, and the results on a self-administered questionnaire about health-related quality of life and a general quality of life questionnaire. Only 371 patients were followed for a total of 24 months.

The following observations can be drawn from the data collected. The 90-day mortality for the surgery group (7.9 percent) is significantly higher than the medical therapy group (1.3 percent). The poor outcome of those considered at high risk reported in the initial publication of this trial (3) was confirmed in this subsequent report. There was no significant difference in overall mortality despite a higher early mortality rate in the surgery group. Even when excluding those patients considered to be at high risk, there was no difference in overall mortality among non-high risk patients. Among patients with predominantly upper lobe emphysema and low exercise capacity, mortality was lower in the surgery group than in the medical therapy group. In contrast, among those with predominantly non-upper lobe emphysema and high exercise capacity, mortality was higher in the surgery group. A significantly greater percentage of patients in the surgery group reported improvement in exercise capacity at all time periods, i.e., at six, 12 and 24 months. Patients in the surgery group were significantly more likely to have improvements in general and health-related quality of life compared to the medical group.

Based on the above, the authors came to the following conclusions. Overall, LVRS increases the chances of improved exercise capacity but does not confer a survival advantage over medical therapy; the functional benefits of LVRS come at the price of increased short-term mortality and morbidity. There is a survival advantage for patients with both predominantly upper lobe emphysema and low baseline exercise capacity. This survival advantage appears to be due to the very high mortality and marked progressive functional limitation of those treated medically. Patients considered at high risk and those with non-upper lobe emphysema and high baseline exercise capacity are poor candidates for LVRS.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.
This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

2. BCBSA. 2003 TEC Assessment; Lung Volume Reduction Surgery for Severe Emphysema.