Lung Volume Reduction Surgery for Severe Emphysema

Preauthorization is required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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<th>Populations</th>
<th>Interventions</th>
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<td>Individuals: • With upper-lobe emphysema</td>
<td>Interventions of interest are: • Lung volume reduction surgery</td>
<td>Comparators of interest are: • Medical management</td>
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Description

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.

Summary of Evidence

For individuals who have upper-lobe emphysema who receive lung volume reduction surgery (LVRS), the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. Findings from the National Emphysema Treatment Trial (NETT), a multicenter RCT, suggest that LVRS is effective at reducing mortality and improving quality of life in select patients with severe emphysema. In subgroup analysis, LVRS offered a survival advantage only in patients not considered high risk who had predominately upper-lobe emphysema and low initial exercise capacity. Patients with upper-lobe emphysema, regardless of initial exercise capacity, experienced significant improvement in exercise capacity and quality of life after LVRS. Other, smaller RCTs have generally had similar findings, though they have tended to be underpowered for some outcomes and did not stratify by distribution of emphysema. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
For individuals who have non-upper-lobe emphysema who receive LVRS, the evidence includes sub-group analysis of a large RCT. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. In the subgroup analysis of NETT, LVRS offered a survival advantage only in patients who had predominately upper-lobe emphysema. For the subgroup with predominately non-upper-lobe emphysema, NETT did not find significant mortality advantages or symptom improvement with LVRS. Although NETT had positive findings for the study population as a whole, given the surgical risks, additional data are needed to confirm the net health outcome in patients with non-upper-lobe emphysema. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Lung volume reduction surgery (LVRS) as a treatment for emphysema may be considered medically necessary in patients with emphysema who meet ALL of the following criteria*:

- Predominantly upper lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)
- Forced expiratory volume in one second (FEV₁):
  - For patients who are younger than 70 years of age the FEV₁ must be no more than 45% of the predicted value
  - For patients who are 70 years of age or older the FEV₁ must be no more than 45% of the predicted value and 15% or more of the predicted value
  - Marked restriction in activities of daily living despite maximal medical therapy
  - Age younger than 75 years
  - Acceptable nutrition status (i.e., 70% to 130% of ideal body weight)
  - Ability to participate in a vigorous pulmonary rehabilitation program
  - No coexisting major medical problems that would significantly increase operative risk
  - Willingness to undertake risk of morbidity and mortality associated with LVRS
  - Abstinence from cigarette smoking for at least four months.

Lung volume reduction surgery is considered investigational in all other patients.

*Patient selection criteria are based on the National Emphysema Treatment Trial (NETT).

Policy Guidelines

The following additional criteria, also from the NETT trial, may provide further information in determining whether a patient is a candidate for LVRS:

- \( \text{PaO}_2 \) on room air 45 mm Hg or more (30 mm Hg or more at elevations of 5,000 feet or higher)
- \( \text{PaCO}_2 \) on room air less than or equal to 60 mm Hg (less than or equal to 55 mm Hg at elevations of 5,000 feet or higher)
- Post-rehabilitation six-minute walk of at least 140 meters, and able to complete three minutes of unloaded pedaling in exercise tolerance test.
## Medicare Advantage

For Medicare Advantage, Lung Volume Reduction Surgery (LVRS) is **medically necessary** when:

1. The patient satisfies all the criteria outlined below:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>History and physical examination</td>
<td>Consistent with emphysema</td>
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<tr>
<td></td>
<td>BMI, &lt; 31.1 kg/m² (men) or &lt; 32.3 kg/m² (women)</td>
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<td>Stable with &lt; 20 mg prednisone (or equivalent) qd</td>
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<tr>
<td>Radiographic</td>
<td>High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema</td>
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<tr>
<td>Pulmonary function (pre-rehabilitation)</td>
<td>Forced expiratory volume in one second (FEV₁) &lt; 45% predicted ≥ 15% predicted if age ≥ 70 years</td>
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<td>Total lung capacity (TLC) &gt; 100% predicted post-bronchodilator</td>
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<td></td>
<td>Residual volume (RV) &gt; 150% predicted post-bronchodilator</td>
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<tr>
<td>Arterial blood gas level (pre-rehabilitation)</td>
<td>PCO₂, &lt; 60 mm Hg (PCO₂, &lt; 55 mm Hg if 1-mile above sea level)</td>
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<tr>
<td></td>
<td>PO₂, &gt; 45 mm Hg on room air (PO₂, &gt; 30 mm Hg if 1-mile above sea level)</td>
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<tr>
<td>Cardiac assessment</td>
<td>Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF &lt; 45%; dobutamine-radiouclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (&gt; 5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)</td>
</tr>
<tr>
<td>Surgical assessment</td>
<td>Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation</td>
</tr>
<tr>
<td>Exercise</td>
<td>Post-rehabilitation six-min. walk of ≥ 140 m; able to complete three min. unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)</td>
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<tr>
<td>Consent</td>
<td>Signed consents for screening and rehabilitation</td>
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<tr>
<td>Smoking</td>
<td>Plasma cotinine level &lt; 13.7 ng/mL (or arterial carboxyhemoglobin &lt; 2.5% if using nicotine products)</td>
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<td>Nonsmoking for four months prior to initial interview and throughout evaluation for surgery</td>
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<tr>
<td>Preoperative diagnostic and therapeutic program adherence</td>
<td>Must complete assessment for and program of preoperative services in preparation for surgery</td>
</tr>
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</table>

In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity (see Medicare Advantage Policy Guidelines);

2. Also, LVRS is **medically necessary** only when performed at facilities that are Medicare approved facilities. (see Medicare Advantage Policy Guidelines).

LVRS is **not medically necessary** in any of the following clinical circumstances:

1. 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 Medicare Advantage Policy Guidelines);
4. The patient presents with FEV-1 less than 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of less than or equal to 20% of predicted value (high-risk group identified October 2001 by the NETT); or

5. The patient satisfies the criteria outlined above in section 1 (of the medically necessary statement) and 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 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

All other indications for LVRS are investigational.

**Medicare Advantage Policy Guidelines**

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing five or 10 watt/minute ramp on 30% oxygen after three minutes of unloaded pedaling.

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

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.

**Background**

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 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.

Research on lung volume reduction surgery has focused on defining the subgroup of patients most likely to benefit from the procedure. Potential benefits of the procedure (e.g., improvement in functional capacity and quality of life) must be weighed against the potential risk of the procedure (e.g., risk of postoperative mortality).

**Regulatory Status**

Lung volume reduction surgery is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.
Related Protocol

Outpatient Pulmonary Rehabilitation

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


