Lung Volume Reduction Surgery for Severe Emphysema

Policy Number: 7.01.71
Origination: 7/1994
Last Review: 3/2019
Next Review: 3/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for lung volume reduction surgery when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Lung volume reduction surgery 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 (FEV-1):
  - For patients who are younger than 70 years of age, the FEV-1 must be no more than 45% of the predicted value.
  - For patients who are 70 years of age or older, the FEV-1 must be no more than 45% of the predicted value and greater than or equal to 15% of the predicted value.
- Marked restriction in activities of daily living despite maximal medical therapy
- Acceptable nutrition status; i.e. 70-130% 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 4 months

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

When Policy Topic is not covered
Lung volume reduction surgery is considered investigational in all other patients.
Considerations
The following additional criteria, also from the NETT trial, may provide further information in determining whether a patient is a candidate for lung volume reduction surgery:

- PaO2 on room air greater than or equal to 45 mm Hg (greater than or equal to 30 mm Hg at elevations of 5,000 feet or higher)
- PaCO2 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 6-minute walk of at least 140 m, and able to complete 3 min. unloaded pedaling in exercise tolerance test

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
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<tbody>
<tr>
<td>Individuals:</td>
<td></td>
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<td>Relevant outcomes include:</td>
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<tr>
<td>With upper-lobe emphysema</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Overall survival</td>
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<td>- Lung volume reduction surgery</td>
<td>- Medical management</td>
<td>Symptoms</td>
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<td>Functional outcomes</td>
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<td>Quality of life</td>
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<td>Treatment-related mortality</td>
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<td>Individuals:</td>
<td>Interventions of interest are:</td>
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<td>Relevant outcomes include:</td>
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<td>With non-upperlobe emphysema</td>
<td>- Lung volume reduction surgery</td>
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<td>Overall survival</td>
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<td>Quality of life</td>
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<td></td>
<td></td>
<td></td>
<td>Treatment-related mortality</td>
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</tbody>
</table>

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.

For individuals who have upper-lobe emphysema who receive 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 subgroup 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.

**Background**

**Emphysema**

Emphysema is an anatomically defined condition characterized by destruction and enlargement of lung alveoli. It is one of the conditions considered as a chronic obstructive pulmonary disease along with chronic bronchitis and small airways disease. The pathogenesis of emphysema is primarily related to cigarette smoking leading to inflammation and recruitment of immune cells to the terminal air spaces of the lung. The resultant extracellular matrix proteolysis damages the lung. Destruction of the gas exchanging air spaces and ineffective repair of the extracellular matrix results in airspace enlargement. Emphysema can be characterized into distinct pathologic subtypes. Centriacinar emphysema is most frequently associated with cigarette smoking, is usually most prominent in the upper lobes and superior segments of the lower lobes, and is focal. Panacinar emphysema is characterized by abnormally large air spaces evenly distributed across acini in the lower lobes. It is associated with α₁-antitrypsin deficiency. Key pulmonary function parameters are the volume of the first forced expiratory volume in 1 second (FEV₁) and the total volume of air exhaled during the spirometry (forced vital capacity [FVC]). Airflow obstruction related to chronic obstructive pulmonary disease is characterized by reduced ratio of FEV₁/FVC and reduction in FEV₁ correlates with long-term mortality risk.¹

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.

Complications from the surgical procedure include death, reintubation, arrhythmias, mechanical ventilation for more than 2 days, pneumonia, wound infection, and persistent air leak.
Research on LVRS has focused on defining the sub-group 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 post-operative mortality.

**Rationale**

The evidence review was created in July 1999. This review was archived from 2005 to 2010, following the 2003 publication of the National Emphysema Treatment Trial (NETT) findings. In 2010, the evidence review returned to active status and had been regularly updated with searches of the MEDLINE database. The most recent literature update was performed through April 9, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Lung Volume Reduction Surgery**

Evidence for this review consists of trials that include patients with and without upper-lobe emphysema. Results were presented for the population as a whole and subgroups of patients. While separate recommendations are provided for each subgroup of patients, all evidence is discussed in this single section.

**Clinical Context and Test Purpose**

The purpose of lung volume reduction surgery (LVRS) in patients who have upper-lobe and non-upper-lobe emphysema is to provide a treatment option that is an improvement in medical management.
The question addressed in this evidence review is: Does LVRS in patients with upper-lobe and non-upper-lobe emphysema improve the net health outcome compared with medical management?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with upper-lobe and non-upper-lobe emphysema who have poor control of their condition through medical therapy.

**Interventions**
The intervention of interest is LVRS.

**Comparators**
Medical management of emphysema includes bronchodilators to relax constricted airways to relieve coughing, shortness of breath, and breathing problems; inhaled corticosteroids to reduce inflammation, and antibiotics to rid bacterial infections such as bronchitis or pneumonia.

**Outcomes**
Emphysema cannot be cured. The goal of LVRS is to relieve symptoms (eg, improve dyspnea and oxygenation) and slow the progression of the disease, thereby improving QOL. Potential harmful outcomes are related to procedural complications: death, reintubation, arrhythmias, mechanical ventilation for more than 2 days, pneumonia, and persistent air leak.

**Timing**
LVRS is a surgical option when patients experience severe dyspnea despite medical therapy and pulmonary rehabilitation.

**Setting**
Individuals receive LVRS as hospital inpatients.

**Randomized Controlled Trials**

**National Emphysema Treatment Trial**
NETT was a large, multicenter, prospective RCT comparing LVRS with optimal medical therapy in patients with severe emphysema. Two-year findings were published by Fishman et al (2003). The trial included 1218 patients, and the analysis was an intention to treat, reporting on outcomes for all randomized patients. The primary outcomes included total, 30-day, and 90-day mortality and maximal exercise capacity. Secondary outcomes included pulmonary function, distance walked in 6 minutes, and self-reported health-related QOL and general QOL. At preliminary analysis, 371 (30%) patients had been followed for a total of 24 months. Primary findings of the Fishman study are summarized in Table 1.
Table 1. National Emphysema Treatment Trial Primary Findings

<table>
<thead>
<tr>
<th>Variables</th>
<th>90-Day Mortality, %</th>
<th>Total Mortality, No. Death/Total</th>
<th>Improvement in Exercise Capacity at 24 Months, %b</th>
<th>Improvement in Quality of Life at 24 Months, %c</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>1.3</td>
<td>7.9</td>
<td>160/610</td>
<td>157/608</td>
</tr>
<tr>
<td>High-risk patientsa</td>
<td>28</td>
<td>0</td>
<td>30/70</td>
<td>42/70</td>
</tr>
<tr>
<td>ULE with low exercise capacity</td>
<td>3.3</td>
<td>2.9</td>
<td>51/151</td>
<td>26/139</td>
</tr>
<tr>
<td>ULE with high exercise capacity</td>
<td>0.9</td>
<td>2.9</td>
<td>39/213</td>
<td>34/206</td>
</tr>
<tr>
<td>Non-ULE, low exercise capacity</td>
<td>0</td>
<td>8.3</td>
<td>28/84</td>
<td>26/65</td>
</tr>
<tr>
<td>Non-ULE, high exercise capacity</td>
<td>0.9</td>
<td>10.1</td>
<td>27/109</td>
<td>14/111</td>
</tr>
</tbody>
</table>


a High risk is defined as those with a forced expiratory volume in 1 second that was ≤20% of the predicted value and either homogeneous emphysema on computed tomography or a carbon monoxide diffusion capacity that was ≤20% of the predicted value.

b Improvement in exercise capacity in patients followed for 24 mo after randomization was defined as an increase in the maximal workload of >10 W from the patient’s postrehabilitation baseline value.

c Improvement in health-related quality of life in patients followed for 24 mo after randomization was defined as a decrease in St. George’s Respiratory Questionnaire score of >8 points (on a 100-point scale) from the patient’s postrehabilitation baseline score.

Conclusions drawn from these data include the following:

- Overall, LVRS increased the chance of improved exercise capacity but did not confer a survival advantage over medical therapy.
- There was a survival benefit for those patients who had 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 were found to be poor candidates for LVRS.

A follow-up analysis of NETT data was published by Naunheim et al (2006), who reported a median follow-up of 4.3 years compared with 2.4 years in the initial full report.3 Seventy percent of randomized patients participated in the follow-up extension conducted in 2003, and 76% participated in the mailed QOL data
collection in 2004. The analysis was done on an intention-to-treat basis, including all 1218 randomized patients.

Overall, LVRS showed a mortality benefit compared with medical therapy. During follow-up, 46.5% (283/608) patients in the LVRS group and 53.1% (324/610) patients in the medical therapy group died (relative risk, 0.85; p=0.02). However, the long-term mortality benefit was limited to the subgroup of participants who had predominately upper-lobe emphysema and low exercise capacity (those found in the initial report to benefit from LVRS; relative risk, 0.57; p=0.01). Moreover, in the subgroup of patients with predominately upper-lobe emphysema and low exercise capacity (n=290), compared with medical therapy, those in the LVRS group were also more likely to have improved exercise capacity throughout 3 years of follow-up testing (p<0.01) and to have an 8-point improvement in QOL through 4-year follow-up testing (p=0.003).

In the subgroup of patients with predominately upper-lobe emphysema and high exercise capacity (n=419), there was no survival benefit associated with LVRS, but there was a significantly greater improvement in exercise capacity over 3 years (p<0.001) and QOL over 4 years (p=0.003). Patients with non-upper-lobe emphysema and either high or low exercise capacity did not significantly benefit from surgery with respect to mortality rates, exercise capacity, or QOL. A limitation of the long-term follow-up study was that fewer than 80% of surviving NETT participants took part.

Sanchez et al (2010) analyzed data from NETT, focusing on patients who met the following criteria: (1) predominantly upper-lobe emphysema and (2) a heterogeneous distribution of emphysema (non-upper-lobe emphysema) defined as a difference of at least 2 points in the severity of emphysema in any 2 zones of the lung on a 0-to-4 severity scale. Of the 1218 patients enrolled in the study, 511 (42%) patients met both criteria, 261 in the LVRS group and 250 in the medical therapy group. Using Kaplan-Meier analysis, the 3-year survival rate was 81% for patients receiving LVRS and 74% for those in the medical group (p=0.05). At 5 years, the estimated survival rate was significantly higher in the LVRS group (70%) compared with the medical therapy group (60%; p=0.02). Maximal exercise capacity (another NETT primary outcome) was a mean of 49 watts in the LVRS group and 38 watts in the medical therapy group at 1 year (p<0.001). At 3 years, exercise capacity in the 2 groups was 43 watts and 38 watts, respectively, and the between-group difference was not statistically significant.

Kaplan et al (2014) reported on long-term outcomes for high-risk patients from NETT. In this subgroup of 140 randomized patients, the mortality rate was higher in the LVRS group than in the medical therapy group for the first 4.4 years, but longer term survival did not differ significantly between the 2 groups. Median survival was 2.14 years (95% confidence interval [CI], 1.20 to 4.07 years) in the LVRS group and 3.12 years (95% CI, 2.79 to 4.27 years) in the medical therapy group (p>0.05).
RCTs Other Than NETT
Miller et al (2006) published a trial evaluating data from 5 centers in Canada (Canadian Lung Volume Reduction Surgery trial).\textsuperscript{6} Eligibility criteria included: age between 40 and 79 years; disabling dyspnea; forced expiratory volume in 1 second (FEV\textsubscript{1}) of no more than 40\% of predicted; diffusing capacity no more than 60\%; and total lung capacity no more than 120\% or residual volume no less than 200\%. After eligibility screening, medical therapy was optimized, and patients randomized to LVRS (n=32) or continued medical therapy (n=30). The trialists had originally planned to enroll 350 subjects, but due to the low proportion of screened subjects who were eligible, recruitment stopped at only 18\% (62/467) of the target. Based on intention-to-treat analysis, the overall 2-year survival rate was similar between groups: 5 (16\%) of 32 patients died in the LVRS group, and 4 (13\%) of 30 died in the medical therapy group (p=0.93). At 3 and 6 months, there were significantly greater improvements from baseline in FEV\textsubscript{1} for the LVRS group compared with the medical therapy group, but the between-group differences in FEV\textsubscript{1} were not significant at 12 and 24 months. This study might have been underpowered to detect differences in outcomes between groups.

Agzarian et al (2013) published long-term results of the Canadian Lung Volume Reduction Surgery trial.\textsuperscript{7} Fifty-two (84\%) of 62 randomized patients were available for follow-up 8 to 10 years posttreatment. One patient was excluded before surgery, and 9 others were lost to follow-up. The proportion of patients surviving 5 and 10 years were 46\% and 7\%, respectively, in the LVRS group and 25\% and 0\% in the control group. According to Kaplan-Meier survival analysis, median survival was 63 months in the LVRS group and 47 months in the control group (p=0.20).

Systematic Reviews
In a systematic review, Huang et al (2011) pooled analyses of patients undergoing LVRS for severe emphysema.\textsuperscript{8} Eight RCTs (total N=1677 patients) published from 1999 to 2010 were included in the analysis. Reviewers found significantly higher odds of mortality in the medical therapy group than in the LVRS group at 3 months (odds ratio, 5.16; 95\% CI, 2.84 to 9.35). They found no statistically significant difference between groups in the mortality rate at 12 months (odds ratio, 1.05; 95\% CI, 0.82 to 1.33).

A 2016 Cochrane review, updating the 2006 meta-analysis, compared the effectiveness of LVRS with standard nonsurgical therapy in improving health outcomes for patients who had severe diffuse emphysema.\textsuperscript{9,10} The search period for the update extended to April 2016. Two new trials, contributing 89 participants (Clarenbach et al [2015]\textsuperscript{11}, and Pompeo et al [2012]\textsuperscript{12}), were identified and incorporated into the review along with long-term follow-up data from the Canadian Lung Volume Reduction Surgery and NETT trials. These additional data resulted in changes to the conclusions of the 2016 update. A summary of the updated results is presented in Table 2. Patients in the surgery group experienced lower overall mortality in the long-term (≥3 years), as well as significant improvements in FEV\textsubscript{1}, QOL, and exercise capacity compared with patients.
receiving only medical management. Patients with upper-lobe emphysema and low exercise capacity benefited most from the LVRS.

A total of 11 RCTs (1760 participants) were included in the updated review. NETT accounted for 68% of review participants. The odds ratio for surgery vs control was 0.76 (95% CI, 0.61 to 0.95).

**Table 2. Systematic Review Results for Surgery vs Control**

<table>
<thead>
<tr>
<th>Overall Mortality</th>
<th>No. of Studies</th>
<th>Odds Ratio (95% CI)</th>
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<tbody>
<tr>
<td><strong>Total population</strong></td>
<td></td>
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</tr>
<tr>
<td>3 months</td>
<td>5</td>
<td>6.2 (3.2 to 11.8)</td>
</tr>
<tr>
<td>6 months</td>
<td>3</td>
<td>4.4 (1.2 to 15.9)</td>
</tr>
<tr>
<td>12 months</td>
<td>3</td>
<td>3.6 (1.3 to 10.3)</td>
</tr>
<tr>
<td>24 months</td>
<td>3</td>
<td>1.0 (0.8 to 1.3)</td>
</tr>
<tr>
<td>≥3 years</td>
<td>2</td>
<td>0.8 (0.6 to 0.9)</td>
</tr>
<tr>
<td><strong>Risk</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>1^a</td>
<td>2.0 (1.0 to 3.9)</td>
</tr>
<tr>
<td>Non-high</td>
<td>1^a</td>
<td>0.9 (0.6 to 1.1)</td>
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<tr>
<td><strong>Lobe and exercise capacity</strong></td>
<td></td>
<td></td>
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<tr>
<td>Upper-lobe, low exercise capacity</td>
<td>1^a</td>
<td>0.5 (0.3 to 0.8)</td>
</tr>
<tr>
<td>Upper-lobe, high exercise capacity</td>
<td>1^a</td>
<td>0.9 (0.5 to 1.5)</td>
</tr>
<tr>
<td>Non-upper-lobe, high exercise capacity</td>
<td>1^a</td>
<td>0.7 (0.4 to 1.5)</td>
</tr>
<tr>
<td>Non-upper-lobe, low exercise capacity</td>
<td>1^a</td>
<td>2.3 (1.1 to 4.6)</td>
</tr>
<tr>
<td><strong>Exercise capacity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shuttle walking distance</td>
<td>5</td>
<td>0.7 (0.4 to 1.0)</td>
</tr>
<tr>
<td><strong>Lung function</strong></td>
<td></td>
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</tr>
<tr>
<td>Forced expiratory volume in 1 second</td>
<td>4</td>
<td>0.2 (0.1 to 0.3)</td>
</tr>
<tr>
<td><strong>Quality of life</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>St. George’s Respiratory Questionnaire</td>
<td>2</td>
<td>-13.8 (-15.7 to -11.8)</td>
</tr>
</tbody>
</table>


^a National Emphyema Treatment Trial study.

A subgroup analysis evaluated which surgical approaches for LVRS were most effective. In most trials, the decision to perform 1 technique over the other was left to the surgeon. Two of the most commonly employed surgical techniques (video-assisted thoracoscopic surgery and median sternotomy) were assessed as a randomized comparison within one of the studies. A small subgroup study (n=148 patients) randomized median sternotomy and video-assisted thoracoscopic surgery at several NETT centers. There were no significant differences in air leak and 30-day mortality rates between the 2 groups (p=0.08 and p=0.39, respectively).

Reviewers raised concern about the validity of using the subgroup distinctions to determine which patients would be most likely to benefit from the procedure or who would be at greatest risk of early mortality due to the low likelihood that additional studies of similar statistical power to NETT will be conducted.

**Nonrandomized Comparative Studies**

Decker et al (2014) reviewed data on 538 patients from the Society of Thoracic Surgeons (STS) database who received LVRS and compared these data with those
of the 608 NETT participants randomized to the surgery group. None of the patients in the STS database had an FEV₁ less than 20% of predicted or carbon monoxide diffusing capacity less than 20% of predicted; thus, these patients would not have been considered high risk in NETT. Moreover, about 10% of patients in the STS database had previous cardiothoracic surgery, and 1.5% had lung cancer, both exclusions in NETT. Overall, the mortality rate within 30 days of LVRS did not differ significantly between the STS database (5.6%) and NETT (3.6%; p=0.113). When database findings were compared with non-high-risk NETT participants, the 30-day mortality rate was significantly higher among patients in the STS database (5.6%) than in NETT (2.2%; p=0.005). This study was descriptive and did not propose patient selection criteria for LVRS.

Summary of Evidence
For individuals who have upper-lobe emphysema who receive LVRS, the evidence includes RCTs and systematic reviews of the trials. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. Findings from the NETT, a multicenter RCT, have suggested 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 to patients not considered at 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 the distribution of emphysema. The evidence is sufficient to determine 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 subgroup 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 to 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Thoracic Society and European Respiratory Society
asserted that, due to the significant complications from the procedure that may result in prolonged hospital stays and morbidity, additional studies would be needed to evaluate minimally invasive techniques that might reduce complications.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
Since November 2005, Medicare has considered lung volume reduction surgery reasonable and necessary for patients with severe upper-lobe-predominant emphysema or severe non-upper-lobe emphysema and low exercise capacity who meet all requirements listed in Table 3.15.

### Table 3. Medicare Criteria

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Criteria</th>
</tr>
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</table>
| History and physical examination        | • Consistent with emphysema  
• Body mass index ≤31.1 kg/m² (men) or ≤32.3 kg/m² (women)  
• Stable with ≤20 mg prednisone (or equivalent) daily |
| Radiographic                            | • High-resolution computer tomography scan evidence of bilateral emphysema                                                              |
| Pulmonary function (prerehabilitation)  | • Forced expiratory volume in 1 s ≤45% predicted (≥15% predicted if age ≥70 y)  
• Total lung capacity ≥100% predicted postbronchodilator  
• Residual volume ≥150% predicted postbronchodilator |
| Arterial partial pressure (prerehabilitation) | • Pco₂ ≤60 mm Hg (Pco₂ ≤55 mm Hg if 1 mile above sea level)  
• Po₂ ≥45 mm Hg on room air (Po₂ ≥30 mm Hg if 1 mile above sea level) |
| Cardiac assessment                      | Approval for surgery by cardiologist if any of the following are present:  
Unstable angina; LVEF cannot be estimated from the echocardiogram; LVEF <45%; dobutamine-radiouclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on ECG at rest) |
| Surgical assessment                     | Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist postrehabilitation                                      |
| Exercise                                | • Postrehabilitation 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and postrehabilitation) |
| Smoking                                 | • Plasma cotinine level ≤13.7 ng/mL (or arterial carboxyhemoglobin ≤2.5% if using nicotine products)  
• Nonsmoking for 4 mo before initial interview and throughout evaluation for surgery |
| Preoperative diagnostic and therapeutic program adherence | • Must complete assessment for and program of preoperative services in preparation for surgery |

ECG: electrocardiogram; LVEF: left ventricular ejection fraction; Pco₂: partial pressure of carbon dioxide; Po₂: partial pressure of oxygen.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in April 2018 did not identify any ongoing or unpublished trials that would likely influence this review.
REFERENCES

Billing Coding/Physician Documentation Information

32491 Removal of lung, other than pneumonectomy; with resection-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed
Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed

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

Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services

Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services

Postdischarge pulmonary surgery services after LVRS, minimum of 6 days of services

ICD10 Codes

J43.0-J43.9 Emphysema code range
J44.0-J44.9 Chronic obstructive pulmonary disease code range (used for emphysema with chronic obstructive bronchitis)

Additional Policy Key Words
N/A

Policy Implementation/Update Information

7/1/94 New policy. Added to surgery section, considered investigational.
3/1/00 No policy statement changes.
3/1/01 No policy statement changes.
3/1/02 No policy statement changes.
3/1/03 No policy statement changes.
3/1/04 Policy statement revised to include medically necessary indications. Remains investigational for those not meeting criteria.
3/1/05 No policy statement changes.
3/1/06 No policy statement changes.
3/1/07 No policy statement changes.
3/1/08 No policy statement changes.
3/1/09 No policy statement changes.
3/1/10 No policy statement changes.
3/1/11 Policy updated. 4-month timeframe added to time for tobacco abstinence, other policy statements unchanged.
3/1/12 No policy statement changes.
3/1/12 FEV-1 criteria in medically necessary statement changed to less than 45% predicted for patients age 70 or younger and greater than 15% predicted for patients over age 70.
3/1/14 No policy statement changes.
3/1/15 No policy statement changes.
3/1/16 No policy statement changes.
1/1/17 Policy statement updated to remove the age limitation (75 years old) to this procedure.
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