Lung volume reduction surgery (LVRS) as a treatment for emphysema may be considered medically necessary in patients 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 1 second (FEV₁):
  - For patients who are younger than 70 years of age, FEV₁ must be no more than 45% of the predicted value
  - For patients who are 70 years of age or older, 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
- 75 years of age or younger
- 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 4 months

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

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

The following additional criteria, also from the National Emphysema Treatment Trial, may provide further information in determining whether a patient is a candidate for lung volume reduction surgery (LVRS):

- \( P_{\text{aO}_2} \) on room air of 45 mm Hg or more (greater than or equal to 30 mm Hg at elevations of greater than or equal to 5000 feet)
- \( P_{\text{aCO}_2} \) on room air less than or equal to 60 mm Hg (less than or equal to 55 mm Hg at elevations of greater than or equal to 5000 feet)
- Postrehabilitation 6-minute walk distance of at least 140 meters, and ability to complete 3 minutes of unloaded pedaling in exercise tolerance test

**Coding**

The following CPT code explicitly describes LVRS:

- **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

The following CPT code describes thoracoscopic lung volume reduction surgery*:

- **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

*The code is unilateral.

The following HCPCS codes describe pre- and postoperative services related to LVRS:

- **G0302**: Preoperative pulmonary surgery services for preparation for LVRS, complete course of services to include a minimum of 16 days of services
7.01.71  
Lung Volume Reduction Surgery for Severe Emphysema

Page 2 of 12

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

**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 in order to reduce symptoms and improve quality of life.

**Related Policies**

- Endobronchial Valves
- Outpatient Pulmonary Rehabilitation

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**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.

**Rationale**

**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 Surgery

Lung volume reduction is a surgical treatment for patients with severe emphysema. The procedure involves 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 mechanical factors such as elastic recoil and diaphragmatic function are improved by reducing the volume of the hyperinflated diseased lung. In addition to changes in the 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., the risk of postoperative mortality).

Literature Review

Lung Volume Reduction Surgery

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

The trial data serving as the basis for our review of the evidence tends to assess populations with and without upper-lobe emphysema. For this reason, while we make distinct recommendations on both populations, we discuss the evidence for both groups together in this section.

Randomized Controlled Trials

National Emphysema Treatment Trial

NETT was a large, multicenter, prospective randomized controlled trial (RCT) comparing lung volume reduction surgery (LVRS) with optimal medical therapy in patients with severe emphysema. Two-year findings were published in 2003 by Fishman et al. The trial included 1218 patients, and the analysis was intention to treat (ITT), 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 quality of life (QOL) and general QOL. At the time of data 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>
<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</th>
<th>Improvement in Quality of Life at 24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>Med Tx</td>
<td>Surg Tx</td>
<td>Med Tx</td>
<td>Surg Tx</td>
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<td>High-risk patients</td>
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<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>
</tbody>
</table>
Lung Volume Reduction Surgery for Severe Emphysema

Variables | 90-Day Mortality | Total Mortality, No. Death/Total | Improvement in Exercise Capacity at 24 Months\(^b\) | Improvement in Quality of Life at 24 Months\(^c\)
---|---|---|---|---
Non-ULE, high exercise capacity | 0.9% | 10.1% | 27/109 | 14/111 | 3% | 3% | 12% | 15%

Med: Medical; Surg: Surgical; Tx: Treatment; ULE: Upper-Lobe Emphysema.

\(^a\) 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:

- 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.

In 2006, a follow-up analysis of data from NETT was published; it 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 extension of follow-up conducted in 2003, and 76% participated in the mailed QOL data collection in 2004. The analysis was done on an ITT 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 [RR], 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; RR=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 higher 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.

In 2010, Sanchez et al analyzed data from NETT further examining factors associated with a positive outcome after LVRS.\(^4\) The analysis focused on patients with predominantly upper-lobe emphysema (ULE) and a heterogeneous distribution of emphysema (non-ULE) 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% in 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%) than in 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, capacity in the 2 groups was 43 watts and 38 watts, respectively, and the between-group difference not statistically significant.

A 2014 study by Kaplan et al reported on long-term outcomes in 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 in 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

Hillerdal et al (2005) conducted a multicenter trial in Sweden evaluating LVRS. Eligibility criteria included age 75 years or younger, forced expiratory volume in 1 second (FEV1) of no more than 35% of predicted normal value; excessive hyperinflation with a residual volume of at least 200% of predicted, with radiologic signs of emphysema and decreased mobility of the diaphragm. Participants were required to complete a 6-week physical training program successfully. Of the 114 patients eligible for the initial training (of 304 evaluated), 3 were unable to complete the program and 5 died before completion; the remaining 106 patients were randomized to continued physical training alone (n=53) or LVRS plus continued physical training for 3 months postsurgery (n=53). A total of 42 (79%) patients in the surgery group and 43 (81%) in the physical training group were followed for 1 year; ITT analysis was used. The primary outcome was health status using the Swedish version of the 36-Item Short-Form Health Survey (SF-36) and the disease-specific St. George’s Respiratory Questionnaire (SGRQ). Both instruments have scores ranging from 0 to 100; in the SF-36, 100 represents the best health status; in the SGRQ, 100 represents poor health status. For both instruments, the minimally important clinical difference was defined as 4 points. In an analysis adjusting for age and sex, there was a significant difference in SGRQ scores at 6 months (mean difference, 14.3 points) and 12 months (mean difference, 14.7 points), favoring the LVRS group. SF-36 total score at follow-up was not reported. At 12 months, there was significantly more improvement in 6 of the 8 SF-36 subscales in the LVRS group than in the physical training group. The researchers only reported the mean difference in the scale scores, not the proportion of patients who achieved a certain level of improvement. Mortality was a secondary outcome. There were 7 (13%) deaths in the LVRS group and 2 (4%) deaths in the physical training group; this difference was not statistically significant (p=0.5), but the study was likely underpowered for this outcome. Six deaths in the LVRS group were caused by respiratory failure and pneumonia; the seventh patient died suddenly at home. Respiratory failure was also the cause of the 2 deaths in the physical training group. The authors pointed out that baseline SGRQ scores were lower than in NETT (59 vs 53, respectively), suggesting a more severely impaired population. The trial did not examine patient outcomes by upper-lobe predominance or initial exercise capacity.

In 2006, Miller et al published a trial with data from 5 centers in Canada (Canadian Lung Volume Reduction Surgery trial). Eligibility criteria included: age between 40 and 79 years; disabling dyspnea; FEV1 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 to 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 ITT 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=0.935). At 3 and 6 months, there were significantly greater improvements from baseline in FEV1 for the LVRS group than for the medical therapy group, but the between-group differences in FEV1 were not significant at 12 and 24 months. For example, the mean difference in FEV1 at 24 months was 0.06 liters. This study may have been underpowered to detect differences in outcomes between groups.
In 2013, Agzarian et al published long-term results of the Canadian Lung Volume Reduction Surgery trial. Fifty-two (84%) of 62 randomized patients were available for the long-term 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).

In 2015, Clarenbach et al reported an RCT assessing 30 patients scheduled for LVRS. The trial compared patients who were immediately treated with LVRS to patients who were treated after a 3-month waiting period. The primary outcomes were physiologic measures (endothelial function) assessed by flow-mediated dilatation of the brachial artery at 3 months (2.9; 95% CI, 2.1 to 3.6; p<0.001) and C-reactive protein (p=NS). In the group treated with immediate LVRS, the secondary outcome of FEV1 improved by 29%. There were no significant differences between groups for the 6-minute walk test or levels of daily activity at 3 months. This trial included patients who had LVRS for either upper-lobe or lower-lobe disease, the latter being an indication not supported by the results of NETT.

**Systematic Reviews**

In a 2011 systematic review, Huang et al published pooled analyses of patients undergoing LVRS for severe emphysema and found a significantly higher odds of mortality in the medical therapy group than in LVRS group at 3 months (odds ratio [OR], 5.16; 95% CI, 2.84 to 9.35); they found no statistically significant differences between groups in mortality rates at 12 months (OR=1.05; 95% CI, 0.82 to 1.33).

A 2016 Cochrane review, updating the 2006 meta-analysis, included 8 RCTs published between 1999 and 2008, gathering all available evidence from RCTs comparing the effectiveness of LVRS with nonsurgical standard therapy in improving health outcomes for patients with severe diffuse emphysema. The search period for this update was September 2008 to April 2016. Two new trials, contributing 89 participants (Clarenbach et al [2015] and Pompeo et al [2012]13), 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 to the 2016 update.

Eleven studies (1760 participants) were included in the review. All were RCTs. NETT accounted for 68% of review participants. Short-term (90 days) and long-term (>36 months) mortality and QOL were the primary outcomes evaluated. Secondary outcomes were FEV1 and 6-minute walk distance.

Reviewers confirmed prior findings of short-term mortality to be higher overall for LVRS than for control. Five studies could be evaluated for 90-day mortality, and the odds ratio for surgery versus control was 6.16 (95% CI, 3.22 to 11.79). However, long-term mortality, calculated using the 2 added studies, favored LVRS. The odds ratio for surgery versus control was 0.76 (95% CI, 0.61 to 0.95).

Statistically significant differences in QOL scores using the long-term follow-up trial data favored LVRS at the end of follow-up. Decreases on SF-36 scores of -13.6 units (95% CI, -15.76 to -11.44 units) and -14.7 units (95% CI, -19.65 to -9.75 units) were greater than the standard for the minimum clinically important reduction of 4 points for this questionnaire.

Pooled results from 5 of the trials demonstrated improvements in FEV1 through the end of follow-up for LVRS. However, the percentages of participants contributing to the outcome decreased over time, in both surgery and medical management groups, due to the poor long-term prognosis for persons affected by chronic severe emphysema.
Change in exercise capacity was demonstrated using the 6-minute walk distance and the shuttle walking test in analysis of pooled data from 5 trials (n=215 participants). The LVRS group showed significantly greater improvement in walking distance compared with the medical control group at the end of follow-up (standardized mean difference, 0.70; 95% CI, 0.42 to 0.98).

A subgroup analysis evaluated which surgical approaches for LVRS were most effective. In most trials, the decision to perform one technique over the other was left to the discretion of 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 substudy (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).

Additional post hoc analyses assessed high- and low-risk participants, the distribution of emphysema (upper vs non-upper-lobe), and participants' exercise capacity (high vs low). Participants identified post hoc as having a high risk of early death from surgery were those with particularly impaired lung function and poor diffusing capacity and/or homogenous emphysema, but these participants did not show higher mortality at the end of follow-up. Participants with upper-lobe-predominant emphysema and low exercise capacity showed no increased short-term mortality and more favorable long-term mortality. This post hoc analysis was similar to that performed as part of the conduct of NETT.

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
In 2014, Decker et al 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.14 None of the patients in the STS database had an FEV1 less than 20% of predicted or a 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 exclusion criteria 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 patients (2.2%; p=0.005). This study was descriptive and did not propose patient selection criteria for LVRS.

Observational Studies
In 2012, Baldi et al retrospectively analyzed longer term follow-up than had been reported in the RCTs discussed above.15 The study included 52 emphysema patients who had LVRS between 1993 and 2000. The 5-year survival rate was 73%, and the 12-year survival rate was 20%. Eleven (21%) of 52 patients underwent lung transplantation at a mean of 52 months after LVRS. In a multivariate model, 2 variables were statistically associated with patient survival: preoperative pulmonary arterial pressure (hazard ratio [HR], 2.11; 95% CI, 0.99 to 4.45) and upper-lobe distribution of emphysema (HR=2.43; 95% CI, 1.10 to 5.36).

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, have suggested that LVRS is effective at reducing mortality and improving quality of life in select patients with severe emphysema.
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**

The American Thoracic Society issued a statement on lung volume reduction surgery (LVRS) in 1996, which preceded publication of National Emphysema Treatment Trial findings. At the time, the American Thoracic Society stated that LVRS appeared to be helpful in some, but not all, patients with advanced emphysema. This statement was archived and has not been updated.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

Since November 2005, Medicare has considered LVRS reasonable and necessary for patients with severe upper-lobe predominant emphysema or severe non-upper-lobe emphysema and low exercise capacity who meet all of the following requirements (see Table 2).

**Table 2. Medicare Criteria**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Criteria</th>
</tr>
</thead>
</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 blood gas level (prerehabilitation) | • P ramp CO₂ ≤ 60 mm Hg (P ramp CO₂ ≤ 55 mm Hg if 1 mile above sea level)  
• P O₂ ≥ 45 mm Hg on room air (P O₂ ≥ 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-radionuclide 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) |
Lung Volume Reduction Surgery for Severe Emphysema

Assessment Criteria

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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in May 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References


### Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Ability to participate in vigorous pulmonary rehabilitation program
  - ADL limitations/restrictions
  - Past medical and surgical treatment(s) and response(s)
  - Smoking history/current status/and cessation duration
  - Documented nutrition status of 70% to 130% of ideal body weight
- Pulmonary function tests
- PaO₂/Paco₂ levels on room air

### Post Service

- Operative report(s)

### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
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<td>CPT®</td>
<td>32491</td>
<td>Removal of lung, other than pneumonectomy; with resection-plication of emphysematous lung(s) (bullos or non-bullos) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed</td>
</tr>
<tr>
<td></td>
<td>32672</td>
<td>Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullos or non-bullos) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed</td>
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### Lung Volume Reduction Surgery for Severe Emphysema

#### HCPCS

<table>
<thead>
<tr>
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<td>Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services</td>
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<tr>
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#### ICD-10 Procedure

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0BBC0ZZ</td>
<td>Excision of Right Upper Lung Lobe, Open Approach</td>
</tr>
<tr>
<td>0BBC4ZZ</td>
<td>Excision of Right Upper Lung Lobe, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0BBDOZZ</td>
<td>Excision of Right Middle Lung Lobe, Open Approach</td>
</tr>
<tr>
<td>0BBD4ZZ</td>
<td>Excision of Right Middle Lung Lobe, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0BBF0ZZ</td>
<td>Excision of Right Lower Lung Lobe, Open Approach</td>
</tr>
<tr>
<td>0BBF4ZZ</td>
<td>Excision of Right Lower Lung Lobe, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0BBOZZ</td>
<td>Excision of Left Upper Lung Lobe, Open Approach</td>
</tr>
<tr>
<td>0BBO4ZZ</td>
<td>Excision of Left Upper Lung Lobe, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0BBH0ZZ</td>
<td>Excision of Lung Lingula, Open Approach</td>
</tr>
<tr>
<td>0BBH4ZZ</td>
<td>Excision of Lung Lingula, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0BBJ0ZZ</td>
<td>Excision of Left Lower Lung Lobe, Open Approach</td>
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<td>Excision of Left Lower Lung Lobe, Percutaneous Endoscopic Approach</td>
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<tr>
<td>0BBK0ZZ</td>
<td>Excision of Right Lung, Open Approach</td>
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<tr>
<td>0BBK4ZZ</td>
<td>Excision of Right Lung, Percutaneous Endoscopic Approach</td>
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<td>Excision of Left Lung, Percutaneous Endoscopic Approach</td>
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<tr>
<td>0BBM0ZZ</td>
<td>Excision of Bilateral Lungs, Open Approach</td>
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<tr>
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<td>Excision of Bilateral Lungs, Percutaneous Endoscopic Approach</td>
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#### ICD-10 Diagnosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>All Diagnoses</td>
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</table>

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>01/01/1995</td>
<td>Policy adopted</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>03/30/1999</td>
<td>Policy statement unchanged after review BCBSA TEC 1999</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>03/07/2001</td>
<td>Review, statement unchanged</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>06/01/2004</td>
<td>MPC adoption from CTAF as consent BCBSA TEC 2003 Vol. 18 No. 17; Policy revised/updated</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>07/01/2005</td>
<td>Administrative review with BCBSA MPP# 7.01.71 statement unchanged</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/01/2010</td>
<td>Policy Revision</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/11/2013</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.