

<b>7.01.71</b>	<b>Lung Volume Reduction Surgery for Severe Emphysema</b>		
<b>Original Policy Date:</b>	January 1, 1995	<b>Effective Date:</b>	August 1, 2024
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 14

## Policy Statement

- I. Lung volume reduction surgery (LVRS) as a treatment for emphysema may be considered **medically necessary** in individuals who meet **all** of the following criteria\*:
  - A. Predominately upper-lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)
  - B. Forced expiratory volume in 1 second (FEV<sub>1</sub>):
    1. For individuals who are younger than 70 years of age, FEV<sub>1</sub> must be no more than 45% of the predicted value
    2. For individuals who are 70 years of age or older, FEV<sub>1</sub> must be no more than 45% of the predicted value and 15% or more of the predicted value
  - C. Marked restriction in activities of daily living, despite maximal medical therapy
  - D. Age younger than 75 years
  - E. Acceptable nutrition status (i.e., 70% to 130% of ideal body weight)
  - F. Ability to participate in a vigorous pulmonary rehabilitation program
  - G. No coexisting major medical problems that would significantly increase operative risk
  - H. Willingness to undertake the risk of morbidity and mortality associated with lung volume reduction surgery
  - I. Abstinence from cigarette smoking for at least 4 months
  
- II. Lung volume reduction surgery is considered **investigational** in **all** other individuals.

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

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

The following additional criteria, also from the National Emphysema Treatment Trial, may further refine the selection of an individual who is a candidate for lung volume reduction surgery (LVRS):

- Arterial partial pressure of oxygen (PaO<sub>2</sub>) 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 [1524 meters])
- Arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>) 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 [1524 meters])
- Post rehabilitation 6-minute walk distance of at least 140 meters, and ability to complete 3 minutes of unloaded pedaling in an exercise tolerance test.

### Coding

See the [Codes table](#) for details.

## 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 to reduce symptoms and improve quality of life.

## Related Policies

- Bronchial 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 the destruction and enlargement of lung alveoli. It is 1 of the conditions considered as a chronic obstructive pulmonary disease (COPD) along with chronic bronchitis and small airway 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  $\alpha_1$ -antitrypsin deficiency. Key pulmonary function parameters are the volume of the first forced expiratory volume in 1 second (FEV<sub>1</sub>) and the total volume of air exhaled during the spirometry (forced vital capacity [FVC]). Airflow obstruction related to COPD is characterized by the reduced ratio of FEV<sub>1</sub>/FVC, and reduction in FEV<sub>1</sub> correlates with long-term mortality risk.<sup>1</sup>

The 2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD) report states that COPD is 1 of the top 3 causes of death globally and 90% of these deaths occur in low- and middle-income countries.<sup>2</sup> Evidence exists that the prevalence of the disease is appreciably higher in smokers and ex-smokers compared to non-smokers, in those  $\geq 40$  years of age compared to those  $< 40$ , and in men compared to women; although, in developed countries with less smoking, the prevalence is approximately equal between men and women. The COPD Genetic Epidemiology (COPDGene<sup>®</sup>) study aimed to determine the influence of race, gender, and GOLD stage on the prevalence of prior COPD diagnosis at enrollment.<sup>3</sup> Results revealed that African-American individuals had increased odds of not having a prior COPD diagnosis at all GOLD stages of airflow obstruction versus non-

Hispanic White individuals ( $p < .0001$ ). Women had higher odds of having a prior COPD diagnosis at all GOLD stages versus men ( $p < .0001$ ).

### **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.

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 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 risks of the procedure (e.g., the risk of postoperative mortality).

A related policy, 7.01.128, evaluates the use of endobronchial valves for patients with severe or advanced emphysema. During this procedure, a one-way valve is inserted into the most diseased lobe of the lung, allowing air to escape but preventing its re-entry. This process results in volume reduction of the treated lobe, potentially improving lung function and quality of life for selected patients.

### **Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## Lung Volume Reduction Surgery

Evidence for this review consists of trials that include individuals 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 Therapy Purpose

The purpose of lung volume reduction surgery (LVRS) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with upper-lobe emphysema and non-upper-lobe emphysema.

The following PICO was used to select literature to inform this review.

### *Populations*

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

### *Interventions*

The therapy being considered is LVRS.

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 to reduce symptoms and improve quality of life. LVRS can be performed through various approaches, including median sternotomy, thoracotomy, video-assisted thoracoscopic surgery (VATS), or robotic-assisted thoracoscopic surgery, depending on factors such as the extent and distribution of the diseased lung tissue, patient characteristics, and surgeon preference.

### *Comparators*

Comparators of interest include medical management, which 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*

The general outcomes of interest are overall survival (OS), symptoms, functional outcomes, quality of life, and treatment-related mortality. Emphysema cannot be cured. The goal of LVRS is to relieve symptoms (e.g., improve dyspnea and oxygenation) and slow the progression of the disease, thereby improving quality of life.

Potential harmful outcomes are related to procedural complications including death, reintubation, arrhythmias, mechanical ventilation for more than 2 days, pneumonia, and persistent air leak.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Randomized Controlled Trials

#### National Emphysema Treatment Trial

The 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).<sup>4</sup> The trial included 1218 patients, and the analysis was an intention-to-treat (ITT), reporting on outcomes for all randomized patients. Enrolled individuals had a median age of 66 years. Over 90% of enrollees were non-Hispanic White individuals in both groups, with non-Hispanic Black individuals a minority of enrollees (3% vs. 4% in the surgery vs. medical therapy groups, respectively). Men comprised approximately 60% of subjects in both treatment groups. 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, self-reported health-related quality of life, and general quality of life. At a preliminary analysis, 371 (30%) patients had been followed for a total of 24 months. The primary findings of the Fishman et al (2003) study are summarized in Table 1.

**Table 1. National Emphysema Treatment Trial Primary Findings**

Variables	90-Day Mortality, %		Total Mortality, No. Death/Total		Improvement in Exercise Capacity at 24 Months, % <sup>b</sup>		Improvement in Quality of Life at 24 Months, % <sup>c</sup>	
	Med Tx	Surg Tx	Med Tx	Surg Tx	Med Tx	Surg Tx	Med Tx	Surg Tx
All patients	1.3	7.9	160/610	157/608	3	15	9	33
High-risk patients <sup>a</sup>	28	0	30/70	42/70	2	7	0	10
ULE with low exercise capacity	3.3	2.9	51/151	26/139	0	30	10	48
ULE with high exercise capacity	0.9	2.9	39/213	34/206	3	15	11	41
Non-ULE, low exercise capacity	0	8.3	28/84	26/65	7	12	7	37
Non-ULE, high exercise capacity	0.9	10.1	27/109	14/111	3	3	12	15

Adapted from Fishman et al (2003).<sup>4</sup>

Med: medical; Surg: surgical; Tx: treatment; ULE: upper-lobe emphysema.

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

<sup>b</sup>Improvement in exercise capacity in patients followed for 24 months after randomization was defined as an increase in the maximal workload of  $>10$  W from the patient's post rehabilitation baseline value.

<sup>c</sup>Improvement in health-related quality of life in patients followed for 24 months 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 post rehabilitation 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 predominately 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.<sup>5</sup> Seventy percent of randomized patients participated in the follow-up extension conducted in 2003, and 76%

participated in the mailed quality-of-life 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) of patients in the LVRS group and 53.1% (324/610) of patients in the medical therapy group died (relative risk [RR], 0.85;  $p=.02$ ). 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;  $p=.01$ ). 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 ( $p<.01$ ) and to have an 8-point improvement in quality of life through 4 years of follow-up testing ( $p=.003$ ).

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 ( $p<.001$ ) and quality of life over 4 years ( $p=.003$ ). 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 quality of life. 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 the NETT, focusing on patients who met the following criteria: (1) predominately 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.<sup>6</sup> 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 ( $p=.05$ ). At 5 years, the estimated survival rate was significantly higher in the LVRS group (70%) compared with the medical therapy group (60%;  $p=.02$ ). 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 ( $p<.001$ ). 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 the NETT.<sup>7</sup> 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 ( $p>.05$ ). Lim et al reevaluated the results from NETT using longitudinal data methodology to report longer-term outcomes.<sup>8</sup> At 5 years, patients who received LVRS versus medical treatment had sustained improvements (measured as % of predicted value) in FEV<sub>1</sub> (+1.47%;  $p<.001$ ), FVC (+3.44%;  $p<.001$ ), and residual volume (-19.49%;  $p<.001$ ). Furthermore, patients who received LVRS versus medical treatment had non-statistically significant improvements in maximum workload (+0.89 watt;  $p=.069$ ) and quality of well-being score (+0.088;  $p=.102$ ).

### Randomized Controlled Trials Other Than The National Emphysema Treatment Trial

Miller et al (2006) published a trial evaluating data from 5 centers in Canada (Canadian Lung Volume Reduction Surgery trial).<sup>9</sup> Eligibility criteria included: age between 40 and 79 years; disabling dyspnea; forced expiratory volume in 1 second (FEV<sub>1</sub>) 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 were 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 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 ( $p=.93$ ). At 3 and 6 months, there were significantly greater improvements from baseline in FEV<sub>1</sub> for the LVRS group compared with the medical therapy group, but the between-group differences in FEV<sub>1</sub> 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.<sup>10</sup> Fifty-two (84%) of 62 randomized patients were available for follow-up 8 to 10 years post treatment. 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 ( $p=.20$ ).

### Systematic Reviews

In a systematic review, Huang et al (2011) pooled analyses of patients undergoing LVRS for severe emphysema.<sup>11</sup> Eight RCTs (N=1677) 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 [OR], 5.16; 95% CI, 2.84 to 9.35). They found no statistically significant difference between groups in the mortality rate at 12 months (OR, 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.<sup>12,13</sup> The search period for the update extended to April 2016. Two new trials, contributing 89 participants (Clarenbach et al [2015]<sup>14</sup>, and Pompeo et al [2012]<sup>15</sup>), 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 ( $\geq 3$  years), as well as significant improvements in FEV<sub>1</sub>, quality of life, 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 (N=1760) were included in the updated review. The NETT accounted for 68% of the review participants. The OR for surgery versus control was 0.76 (95% CI, 0.61 to 0.95).

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

Overall Mortality	No. of Studies	OR (95% CI)
<b>Total population</b>		
3 months	5	6.2 (3.2 to 11.8)
6 months	3	4.4 (1.2 to 15.9)
12 months	3	3.6 (1.3 to 10.3)
24 months	3	1.0 (0.8 to 1.3)
$\geq 3$ years	2	0.8 (0.6 to 0.9)
<b>Risk</b>		
High	1 <sup>a</sup>	2.0 (1.0 to 3.9)
Non-high	1 <sup>a</sup>	0.9 (0.6 to 1.1)
<b>Lobe and exercise capacity</b>		
Upper-lobe, low exercise capacity	1 <sup>a</sup>	0.5 (0.3 to 0.8)
Upper-lobe, high exercise capacity	1 <sup>a</sup>	0.9 (0.5 to 1.5)
Non-upper-lobe, high exercise capacity	1 <sup>a</sup>	0.7 (0.4 to 1.5)
Non-upper-lobe, low exercise capacity	1 <sup>a</sup>	2.3 (1.1 to 4.6)
<b>Exercise capacity</b>		<b>SMD (95% CI)</b>
Shuttle walking distance	5	0.7 (0.4 to 1.0)
<b>Lung function</b>		
FEV <sub>1</sub>	4	0.2 (0.1 to 0.3)

Overall Mortality	No. of Studies	OR (95% CI)
<b>Quality of life</b>		
<b>St. George's Respiratory Questionnaire</b>	2	-13.8 (-15.7 to -11.8)

Adapted from van Agteren et al (2016).<sup>12</sup>

CI: confidence interval; FEV<sub>1</sub>: forced expiratory volume in 1 second; OR: odds ratio; SMD: standard mean difference.

<sup>a</sup>National Emphysema 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 1 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=.08 and p=.39, respectively).

Reviewers raised a 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 the 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.<sup>16</sup> None of the patients in the STS database had an FEV<sub>1</sub> 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 the 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 the NETT (3.6%; p=.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 the NETT (2.2%; p=.005). This study was descriptive and did not propose patient selection criteria for LVRS.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Thoracic Society and European Respiratory Society

In 2015, the American Thoracic Society and the European Respiratory Society published a joint statement on current research questions for chronic obstructive pulmonary disease.<sup>17</sup> The statement discussed lung volume reduction surgery (LVRS) and 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.



### National Institute for Health and Care Excellence

In 2005, the National Institute for Health and Care Excellence (NICE) published interventional procedures guidance on the use of LVRS for advanced emphysema.<sup>18</sup> The guidance suggests that LVRS for advanced emphysema appears adequate to support the use of this procedure, given the current evidence of safety and efficacy. The guidance stipulates that patient selection is important due to the mortality risk for severely compromised lung function and that the procedure should be undertaken by a team including a respiratory physician, thoracic surgeon, and specialists in pulmonary rehabilitation.

### 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 requirements listed in Table 3.<sup>19</sup>

**Table 3. Medicare Criteria**

Assessment	Criteria
<b>History and physical examination</b>	<ul style="list-style-type: none"> <li>• Consistent with emphysema</li> <li>• BMI <math>\leq 31.1</math> kg/m<sup>2</sup> (men) or <math>\leq 32.3</math> kg/m<sup>2</sup> (women)</li> <li>• Stable with <math>\leq 20</math> mg prednisone (or equivalent) daily</li> </ul>
<b>Radiographic</b>	<ul style="list-style-type: none"> <li>• High-resolution computed tomography scan evidence of bilateral emphysema</li> </ul>
<b>Pulmonary function (prerehabilitation)</b>	<ul style="list-style-type: none"> <li>• FEV<sub>1</sub> <math>\leq 45\%</math> predicted (<math>\geq 15\%</math> predicted if age <math>\geq 70</math> y)</li> <li>• Total lung capacity <math>\geq 100\%</math> predicted postbronchodilator</li> <li>• Residual volume <math>\geq 150\%</math> predicted postbronchodilator</li> </ul>
<b>Arterial partial pressure (prerehabilitation)</b>	<ul style="list-style-type: none"> <li>• Pco<sub>2</sub> <math>\leq 60</math> mm Hg (Pco<sub>2</sub> <math>\leq 55</math> mm Hg if 1 mile above sea level)</li> <li>• Po<sub>2</sub> <math>\geq 45</math> mm Hg on room air (Po<sub>2</sub> <math>\geq 30</math> mm Hg if 1 mile above sea level)</li> </ul>
<b>Cardiac assessment</b>	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)
<b>Surgical assessment</b>	<ul style="list-style-type: none"> <li>• Approval for surgery by a pulmonary physician, thoracic surgeon, and anesthesiologist post rehabilitation</li> </ul>
<b>Exercise</b>	<ul style="list-style-type: none"> <li>• Post rehabilitation 6-min walk of <math>\geq 140</math> m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)</li> </ul>
<b>Smoking</b>	<ul style="list-style-type: none"> <li>• Plasma cotinine level <math>\leq 13.7</math> ng/mL (or arterial carboxyhemoglobin <math>\leq 2.5\%</math> if using nicotine products)</li> <li>• Nonsmoking for 4 months before initial interview and throughout evaluation for surgery</li> </ul>
<b>Preoperative diagnostic and therapeutic program adherence</b>	<ul style="list-style-type: none"> <li>• Must complete assessment for and program of preoperative services in preparation for surgery</li> </ul>

BMI: body mass index; ECG: electrocardiogram; FEV<sub>1</sub>: forced expiratory volume in 1 second; LVEF: left ventricular ejection fraction; Pco<sub>2</sub>: partial pressure of carbon dioxide; Po<sub>2</sub>: partial pressure of oxygen.

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

## References

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education+surgery&

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## Documentation for Clinical Review

### Please provide the following documentation:

- 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 including FEV1
- Pao<sub>2</sub>/Paco<sub>2</sub> levels on room air

### Post Service (in addition to the above, please include the following):

- Operative report(s)

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	32491	Removal of lung, other than pneumonectomy; with resection-plectomy of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed
	32672	Thoracoscopy, surgical; with resection-plectomy for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed
HCPCS	G0302	Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services
	G0303	Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services
	G0304	Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services
	G0305	Post discharge pulmonary surgery services after LVRS, minimum of 6 days of services

## Policy History

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

Effective Date	Action
01/01/1995	Policy adopted
03/30/1999	Policy statement unchanged after review BCBSA TEC 1999
03/07/2001	Review, statement unchanged
06/01/2004	MPC adoption from CTAF as consent BCBSA TEC 2003 Vol. 18 No. 17; Policy revised/updated
07/01/2005	Administrative review with BCBSA MPP# 7.01.71 statement unchanged
10/01/2010	Policy Revision
01/11/2013	Policy revision with position change
05/29/2015	Coding update
08/01/2016	Policy title change from Lung Volume Reduction Surgery Policy revision without position change
08/01/2017	Policy revision without position change
08/01/2018	Policy revision without position change
08/01/2019	Policy revision without position change
08/01/2020	Annual review. No change to policy statement. Literature review updated.
08/01/2021	Annual review. No change to policy statement. Literature review updated.
08/01/2022	Annual review. Policy statement, guidelines and literature updated.
08/01/2023	Annual review. No change to policy statement.
10/01/2023	No change to policy statement. Literature review updated.
08/01/2023	Annual review. Policy statement, guidelines and literature updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**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 and Feedback (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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*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.*

**Appendix A**

POLICY STATEMENT	
BEFORE <span style="color: red;">Red font: Verbiage removed</span>	AFTER <span style="color: blue;">Blue font: Verbiage Changes/Additions</span>
<p><b>Lung Volume Reduction Surgery for Severe Emphysema 7.01.71</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Lung volume reduction surgery (LVRS) as a treatment for emphysema may be considered <b>medically necessary</b> in individuals who meet <b>all</b> of the following criteria*:                             <ol style="list-style-type: none"> <li>A. Predominantly upper-lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)</li> <li>B. Forced expiratory volume in 1 second (FEV<sub>1</sub>):                                     <ol style="list-style-type: none"> <li>1. For individuals who are younger than 70 years of age, FEV<sub>1</sub> must be no more than 45% of the predicted value</li> <li>2. For individuals who are 70 years of age or older, FEV<sub>1</sub> must be no more than 45% of the predicted value and 15% or more of the predicted value</li> </ol> </li> <li>C. Marked restriction in activities of daily living, despite maximal medical therapy</li> <li><span style="color: red;">D. 75 years of age or younger</span></li> <li>E. Acceptable nutrition status (i.e., 70% to 130% of ideal body weight)</li> <li>F. Ability to participate in a vigorous pulmonary rehabilitation program</li> <li>G. No coexisting major medical problems that would significantly increase operative risk</li> <li>H. Willingness to undertake the risk of morbidity and mortality associated with <b>LVRS</b></li> <li>I. Abstinence from cigarette smoking for at least 4 months</li> </ol> </li> <li>II. Lung volume reduction surgery is considered <b>investigational</b> in <b>all</b> other individuals.</li> </ol> <p>* Patient selection criteria are based on the National Emphysema Treatment Trial.</p>	<p><b>Lung Volume Reduction Surgery for Severe Emphysema 7.01.71</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Lung volume reduction surgery (LVRS) as a treatment for emphysema may be considered <b>medically necessary</b> in individuals who meet <b>all</b> of the following criteria*:                             <ol style="list-style-type: none"> <li>A. Predominately upper-lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)</li> <li>B. Forced expiratory volume in 1 second (FEV<sub>1</sub>):                                     <ol style="list-style-type: none"> <li>1. For individuals who are younger than 70 years of age, FEV<sub>1</sub> must be no more than 45% of the predicted value</li> <li>2. For individuals who are 70 years of age or older, FEV<sub>1</sub> must be no more than 45% of the predicted value and 15% or more of the predicted value</li> </ol> </li> <li>C. Marked restriction in activities of daily living, despite maximal medical therapy</li> <li><span style="color: blue;">D. Age younger than 75 years</span></li> <li>E. Acceptable nutrition status (i.e., 70% to 130% of ideal body weight)</li> <li>F. Ability to participate in a vigorous pulmonary rehabilitation program</li> <li>G. No coexisting major medical problems that would significantly increase operative risk</li> <li>H. Willingness to undertake the risk of morbidity and mortality associated with <span style="color: blue;">lung volume reduction surgery</span></li> <li>I. Abstinence from cigarette smoking for at least 4 months</li> </ol> </li> <li>II. Lung volume reduction surgery is considered <b>investigational</b> in <b>all</b> other individuals.</li> </ol> <p>* Patient selection criteria are based on the National Emphysema Treatment Trial.</p>