Lung Volume Reduction Surgery for Severe Emphysema

Policy Number: 7.01.71  Last Review: 3/2017

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 of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
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<tbody>
<tr>
<td>Individuals:</td>
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<td>Medical management</td>
<td>Overall survival</td>
</tr>
<tr>
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<td>Symptoms</td>
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<td>Functional outcomes</td>
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<td>Treatment-related mortality</td>
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<tr>
<td>With non-upperlobe emphysema</td>
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<td>Symptoms</td>
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<td>Treatment-related mortality</td>
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</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
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.

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 with a search of the MEDLINE database. The document was on "no further review" status 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 has been updated regularly with MEDLINE searches. The most recent literature review was conducted through April 27, 2016. Following is a summary of the key published literature to date.

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 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, %</th>
<th>Improvement in Quality of Life at 24 Months, %</th>
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<tbody>
<tr>
<td>All patients</td>
<td>1.3%</td>
<td>7.9%</td>
<td>160/610</td>
<td>157/608</td>
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<tr>
<td>High-risk patientsa</td>
<td>28%</td>
<td>0%</td>
<td>30/70</td>
<td>42/70</td>
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<tr>
<td>ULE with low exercise capacity</td>
<td>3.3%</td>
<td>2.9%</td>
<td>51/151</td>
<td>26/139</td>
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<tr>
<td>ULE with high exercise capacity</td>
<td>0.9%</td>
<td>2.9%</td>
<td>39/213</td>
<td>34/206</td>
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<tr>
<td>Non-ULE, low exercise capacity</td>
<td>0%</td>
<td>8.3%</td>
<td>28/84</td>
<td>26/65</td>
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<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:

- 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. 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 an improvement in 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 in terms of 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 the study extension.

In 2010, Sanchez et al published an analysis of data from NETT further examining factors associated with a positive outcome after LVRS. The analysis focused on patients with upper-lobe predominance and a heterogeneous distribution of emphysema defined as a difference of at least 2 points in 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 of these 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 the medical group (p=0.05). At 5 years, the estimated survival rate was significantly higher in the LVRS group (70%) than the medical therapy group (60%; p=0.02). Maximal exercise capacity, another NETT primary outcome, was a mean of 49 W in the LVRS group and 38 W in the medical therapy group at 1 year (p<0.001). At 3 years, capacity in the 2 groups was 43 W and 38 W, respectively, and the between-group difference was 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) in the LVRS group and 3.12 years (95% CI, 2.79 to 4.27) in the medical therapy group (p>0.05).

**Systematic Reviews**
Additional RCTs evaluating LVRS for treating emphysema have been published as well as 2 meta-analyses of these RCTs.\(^5\,^6\) Each meta-analysis included 8 RCTs published between 1999 and 2006. However, NETT accounted for about 75% of the patients in both meta-analyses, limiting the usefulness of the findings of the pooled analyses. In the more recent meta-analysis, pooled analyses found a significantly higher odds of mortality in the medical therapy group than in LVRS at 3 months (odds ratio [OR], 5.16; 95% CI, 2.84 to 9.35) and no statistically significant difference between groups in mortality at 12 months (OR=1.05; 95% CI, 0.82 to 1.33).\(^6\) The authors did not conduct subgroup analyses (eg, by location of emphysema, exercise capacity, or heterogeneity of emphysema).

**RCTs Other Than NETT**
Hillerdal et al (2005) conducted a multicenter study in Sweden evaluating LVRS.\(^7\) 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 successfully complete a 6-week physical training program. 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 scale 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 mean difference in the scales, 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 of the 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 study did not examine patient outcomes by upper-lobe predominance or initial exercise capacity.

In 2006, Miller et al published a study with data from 5 centers in Canada (Canadian Lung Volume Reduction Surgery [CLVRS] trial).\(^8\) Eligibility criteria included: age between 40 and 79 years; disabling dyspnea; FEV\(_1\) 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 were randomized to LVRS (n=32) or continued medical therapy (n=30). The researchers 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 target. Based on ITT analysis, 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 months and 6 months, there was a significantly greater improvement from baseline in FEV\(_1\) for the LVRS group than for the medical therapy group, but the between-group differences in FEV\(_1\) were not significant at 12 and 24 months. For example, the mean difference in FEV\(_1\) at 24 months was 0.06 L. This study may have been underpowered to detect differences in outcomes between groups.

In 2013, Agzarian et al published long-term results of the CLVRS trial.\(^9\) Fifty-two (84%) of 62 randomized patients were available for the long-term follow-up 8 to 10 years after 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=0.20).

In 2015, Clarenbach et al reported an RCT in 30 patients scheduled for LVRS.\(^{10}\) 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 a 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 FEV\(_1\) 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.

**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.\(^{11}\) None of the patients in the STS database had an FEV\(_1\) 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. And, 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 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 conducted a retrospective analysis that included longer term follow-up than had been reported in the RCTs discussed above. 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 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).

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in June 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**

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

For individuals who have non-upper-lobe emphysema who receive LVRS, the evidence includes sub-group analysis of a large RCT. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality. In the subgroup analysis of NETT, LVRS offered a survival advantage only in patients who had predominately upper-lobe emphysema. For the subgroup with predominately non-upper-lobe emphysema, NETT did not find significant mortality advantages or symptom improvement with LVRS. Although NETT had positive findings for the study population as a whole, given the surgical risks, additional data are needed to confirm the net health outcome in patients...
with non-upper-lobe emphysema. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**
The American Thoracic Society (ATS) issued a statement on LVRS in 1996, which preceded publication of NETT findings. At the time, ATS 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 January 1, 2004, 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):[14]

**Table 2. Medicare Criteria**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Criteria</th>
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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 |
| Arterial blood gas level (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-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) |
| Consent | Signed consents for screening and rehabilitation |
| 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.
There are additional criteria specifying eligible facilities.

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

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

**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**
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**

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.