Clinical Policy Title: Lung volume reduction surgery

Clinical Policy Number: 07.03.03

Effective Date: April 1, 2018
Initial Review Date: February 6, 2018
Most Recent Review Date: March 6, 2018
Next Review Date: March 2019

Related policies:

CP# 07.02.05 Pulmonary rehabilitation
CP# 07.02.06 Mechanical airway clearance device
CP# 07.02.07 Lung transplant
CP# 07.02.09 Alemtuzumab induction therapy in lung transplantation

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of lung volume reduction surgery for emphysema to be clinically proven, and therefore medically necessary, when all of the following criteria are met:

1. The member has a history and physical examination documenting severe upper lobe emphysema or severe non-upper lobe emphysema with low exercise capacity.
2. The forced expiratory volume in one second for the member is 45 percent or less of that predicted (≥ 15 percent if the member is at least age 70).
3. Significant functional limitation persists after six to 12 weeks of pulmonary rehabilitation while receiving optimal medical therapy.
4. Hyperinflation is demonstrated by total lung capacity of more than 100 percent of the predicted value and residual volume of more than 150 percent of the predicted value.
5. The member’s partial pressure of carbon dioxide of 60 mmHg or lower (≤ 55 mmHg if one mile above sea level).
6. The member’s partial pressure of oxygen is 45 mmHg or higher on room air (≥ 30 mmHg if one mile above sea level).
7. The member’s body mass index is 31.1 kg/m\(^2\) or less (men) or 32.3 kg/m\(^2\) or less (women).
8. The member is stable with no more than 20 mg of prednisone (or equivalent) four times a day.
9. The member has not smoked for at least four months before treatment.
10. The member undergoes a preoperative six- to 10-week series of 16 to 20 preoperative pulmonary rehabilitation sessions, each a minimum of two hours.
11. The member undergoes a postoperative six- to 10-week series, each a minimum of two hours, of pulmonary rehabilitation sessions, within eight to nine weeks of the surgery.
12. The member has no comorbid conditions that would significantly increase surgical risk.
13. Treatment is performed at facilities identified by the National Heart, Lung, and Blood Institute as meeting the threshold for participation in the National Emphysema Treatment Trial and at sites approved by Medicare as lung transplant facilities (Fishman, 2001; Fishman, 2003; CMS, 2003; DeCamp, 2008b).

Limitations:

Lung volume reduction surgery is not clinically proven, and therefore not medically necessary, for high-risk patients with severe emphysema. A high-risk patient has a forced expiratory volume in the first second that is 20 percent or less of their predicted value and either homogenous distribution of emphysema on computed tomography scan or low carbon monoxide-diffusing capacity that is 20 percent or less of their predicted value.

Lung volume reduction surgery is not clinically proven and therefore not medically necessary for non-high-risk patients who satisfy the exclusion criteria from the National Emphysema Treatment Trial protocol and who have severe non-upper-lobe emphysema with high exercise capacity (CMS, 2003; DeCamp, 2008b).

Alternative covered services:

- Lung transplantation.
- Medical treatments of emphysema.

Background

Emphysema is a chronic and progressive disease of the lung, marked by the destruction of the alveoli, which are sacs that promote oxygen transfer between air and bloodstream. The condition is marked by shortness of breath and destruction or reduction in elasticity in alveolar walls. Along with bronchitis, it is one of the two conditions classified as a chronic obstructive pulmonary disease (ALA, 2013). Prevalence of emphysema in the U.S. rose from 14.0 to 20.2 per 1000 persons between 1999 and 2011. In 2011, 4.7 million Americans had the disease, which was up from 2.8 million in 1999. White non-Hispanics have the highest 2011 rate of any racial or ethnic group (23.9 per 1000 persons), while
Hispanics have the lowest at 7.1 per 1000; rates are increasing for all groups. Emphysema prevalence is slightly higher in females and much higher in the elderly (ALA, 2013). The age-adjusted U.S. rate of mortality from emphysema has declined 72 percent from 1999 to 2016 (CDC, 2017).

Emphysema can be treated using various methods. Bronchodilators, which are medications that relax the muscles in the lung to improve respiration, are a common treatment. Corticosteroids, generated through inhalers, are another established therapy. Oral steroids, such as prednisone, can also be used. Oxygen supplementation using air from tanks is another therapy. Some patients may need surgery and ensuing rehabilitation (Kim, 2015).

Lung volume reduction surgery, also referred to as reduction pneumoplasty, lung shaving, or lung contouring, was first attempted in 1957 to reduce pulmonary hyperinflation by removing over-distended and nonfunctional areas of the lungs. The procedure restores elastic recoil of the lungs, opens small airways, and improves ventilator mechanics. Surgery is performed using a median sternotomy involving an incision in the breast bone to expose the lungs or the less-invasive video-assisted thoracoscopic surgery of three small incisions between ribs and a videoscope to guide surgery. Damaged lung tissue is removed and the remaining tissue is stapled together. The most common complication is air leakage through stapled lung tissue. Chest tubes are required to monitor this leakage (CMS, 2003).

The decision to recommend lung volume reduction surgery for patients with emphysema involves extensive evaluation and preparation to minimize perioperative risks and optimize surgical outcomes. Initial screening includes spirometry, diffusion capacity, lung volumes by body plethysmography, and high-resolution computed tomography scanning. Good candidates for surgery include those who meet the following criteria:

1. Age younger than 75 years.
2. Emphysema by clinical evaluation.
3. Non-smoker, or ex-smoker for more than four months.
4. Clinically stable, receiving no more than 20 mg prednisone daily.
5. Significant functional limitation after six to 12 weeks of pulmonary rehabilitation with optimal medical therapy.
6. Demonstrated compliance with medical regimen.
7. Post-bronchodilator-forced expiratory volume of less than 45 percent predicted for all ages and more than 15 percent if older than 70 years.
8. Hyperinflation demonstrated by total lung capacity of more than 100 percent of predicted and residual volume more than 150 percent of predicted.
9. Post-rehabilitation six-minute walk distance of more than 140 m.
10. Low post-rehabilitation exercise capacity (demonstrated by maximal achieved cycle ergometry watts).
11. High-resolution computed tomography demonstrating bilateral severe emphysema, ideally with upper-lobe predominance (DeCamp, 2008b).
The National Emphysema Treatment Trial, which compared outcomes of lung volume reduction surgery with medical treatment, helped define medical necessity of the surgery (Fishman, 2001; Fishman, 2003).

The U.S. Centers for Medicare & Medicaid Services issued a coverage decision memo for lung volume reduction surgery on August 20, 2003. The memo specified the conditions for coverage for patients with emphysema, which were based largely on the just-completed National Emphysema Treatment Trial (CMS, 2003).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 5, 2018. Search terms were: “lung volume reduction surgery.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

A review of Medicare records documented that only 119 lung volume reduction surgery procedures were performed in the U.S. in 2008. After determining that 15 percent of a sample of Medicare patients with advanced emphysema met clinical profile and anatomy criteria, authors concluded that the procedure is under-utilized (Akuthota, 2012). A study documented 3,307 procedures were performed in the U.S. from 2000 to 2010, with the number declining over time. In-hospital mortality was 6.1 percent, and average length of stay was nine days; neither changed over time. A total of 7.9 percent of patients required tracheostomy.

Predictors of in-hospital mortality were age (older than age 65), presence of interstitial lung disease, and malnutrition, with odds ratios of 2.83, 2.81, and 2.74, respectively (Ahmad, 2014). The declining number
of these procedures reflects the focus on developing less-invasive interventions after the National Emphysema Treatment Trial (Criner, 2011).

In the National Emphysema Treatment Trial, which helped define necessity of lung volume reduction surgery, patients with emphysema who underwent surgery were compared with those who had medical treatment. Researchers assessed outcomes in patients with a forced expiratory volume in one second less than 20 percent of their predicted value, and either a homogeneous distribution of emphysema on computed tomography or a carbon monoxide-diffusing capacity less than 20 percent of their predicted value. Patients had a 16-percent, 30-day mortality rate after surgery compared with no deaths after medical treatment, a difference significant at \( P < 0.001 \). Those who survived surgery had superior distance walked in six minutes \( (P = 0.03) \) and forced expiratory volume \( (P < 0.001) \) but a similar health-related quality of life (Fishman, 2001).

The trial \( (n = 1,218) \) eventually found similar death rates per person-year \( (0.11) \) in both groups. After 24 months, exercise capacity was superior in patients who had had surgery \( (15 \text{ percent versus 3 percent improved more than 10 W}; P < 0.001) \). Patients with predominantly upper-lobe emphysema and low exercise capacity who had had surgery had lower mortality than comparable patients who had had medical treatment \( (P = 0.005) \). Patients with non-upper-lobe emphysema and high exercise capacity who had had surgery had higher mortality \( (P = 0.02) \) (Fishman, 2003).

A follow-up of the National Emphysema Treatment Trial \( (n = 511 \text{ of the original 1,218 subjects}) \) resulted in a longer-term review of outcomes. Surgery, compared with medical treatment, resulted in a five-year survival benefit \( (70 \% \text{ versus 60 percent}, P = 0.02) \); a three-year reduction of residual volume reduction \( (25 \% \text{ versus 2 percent}, P < 0.001) \); higher University of California-San Diego dyspnea score \( (16 \text{ points versus 0 points}, P < 0.001) \); and improved St. George’s Respiratory Questionnaire quality of life score \( (12 \text{ points versus 0 points}, P < 0.001) \) (Sanchez, 2010).

A systematic review and meta-analysis of eight trials \( (n = 1,677) \) compared outcomes for patients with severe emphysema who underwent lung volume reduction surgery with those who received conservative medical therapies. Mortality in the surgical group was elevated, but the excess declined with time after surgery \( (\text{odds ratio at three, six, and 12 months were 5.16, 3.00, and 1.05, respectively}) \). Lung function indices for the surgical group improved over time. Quality of life of the surgical group was better at six and 12 months. Video-assisted thoracoscopic surgery was performed more frequently than median sternotomy due to earlier recovery and lower utilization (Huang, 2011).

A review of seven studies compared lung volume reduction surgery and medical treatment outcomes for severe emphysema. Patients who had had surgery had higher quality of life scores \( (45.3 \text{ versus 27.5}, P < 0.001) \), improved maximum ventilation \( (32.8 \text{ L/min versus 29.6 L/min}, P = 0.001) \), and lower exacerbation rate per person-year \( (0.27 \text{ percent versus 0.37 percent}, P = 0.0005) \). Mortality for the surgical group, which was higher than the medical group soon after surgery, equaled the medical group at three years \( (P = 0.15) \) and was lower after four years \( (\text{borderline significant at } P = 0.06) \) similar to another study (Kaplan, 2014). Patients with upper-lobe predominant disease and low exercise capacity
(0.36 versus 0.54, \( P = 0.003 \)) had the greatest five-year mortality benefit from undergoing surgery than patients with non-upper-lobe disease (0.38 versus 0.45, \( P = 0.03 \)) or upper-lobe disease with high exercise capacity (0.33 versus 0.38, \( P = 0.32 \)). Five studies found patients who had had surgery had greater six-minute walking distances (433 m versus 300 m, \( P < 0.002 \)), improved total lung capacity (18.8 percent versus 7.9 percent predicted, \( P < 0.02 \)), and quality of life scores (47.0 versus 23.2, \( P < 0.05 \)) (Zahid, 2011). These results confirmed similar results in an earlier meta-analysis of eight randomized trials (Berger, 2005) and a long-term follow-up of the National Emphysema Treatment Trial (Naunheim, 2006).

A Cochrane review of 11 studies (\( n = 1,760 \)) assessed randomized controlled trials comparing outcomes of lung volume reduction surgery with standard medical care (eight of the studies) and other techniques. Short-term mortality was significantly higher (odds ratio = 6.16) but was significantly lower long term (odds ratio = 0.76) for patients who had had surgery. Patients with upper lobe-predominant emphysema and low baseline exercise capacity showed the best mortality outcomes (Van Agteren, 2016).

The Society of Thoracic Surgeons Database followed 538 patients who underwent lung volume reduction surgery from 2003 to 2011 and compared results with those of the earlier National Emphysema Treatment Trial. The more recently treated patients were younger \( (P < 0.001) \), a larger proportion underwent the procedure thoracoscopically \( (P < 0.001) \), and forced expiratory volume in one second was 31 percent, which was higher than the earlier 28 percent \( (P < 0.001) \). Mortality was 3 percent higher \( (P = 0.005) \) in later subjects, because patients were high-risk compared with those who were non-high risk in the trial (Decker, 2014).

Air leaks from stapled tissue after lung volume reduction surgery have always been the most common adverse effect of the surgery. Consequences can include longer hospital stays, readmission to intensive care, prolonged need for thoracostomy and adjunctive treatment, and a higher rate of infections and cardiac complications. Early estimates of incidence of prolonged leaks, defined as seven days or longer, range from 46 percent to 80 percent of patients undergoing surgery; during the National Emphysema Treatment Trial, 50 percent of the 552 patients experienced prolonged leaks (Nicotera, 2010).

One study compared prolonged air leak rates in 134 patients undergoing lung volume reduction surgery for those remaining awake (sole epidural anesthesia) with those under general anesthesia. The “awake” group had significantly fewer patients with prolonged air leaks (18 percent versus 40 percent, \( P = 0.007 \)) and shorter average periods of leak (5.2 versus 7.9 days, \( P < 0.0002 \)) (Tacconi, 2009).

Some patients undergo repeat lung volume reduction surgery. One study reviewed 22 such patients a median of 5.0 years after the initial surgery. Procedures were performed with a video-assisted thoracoscopic technique in 19 patients and with thoracotomy in the others. No deaths occurred in the first 90 days after surgery. Median hospital stay after the second surgery was significantly longer (14 versus nine days). Re-operations due to persistent air leak were necessary in 32 percent of patients. No
complications occurred in 23 percent of patients. Authors conclude that repeat surgeries can be performed as a palliative treatment (Kostron, 2015).

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Van Agteren (2016) | **Key points:**  
| Mortality after lung volume reduction surgery vs. other treatment, and by types of patients |  
|                  | • Cochrane review, 11 randomized controlled trials (n = 1,760) on outcomes of lung volume reduction surgery.  
|                  | • Eight studies compared with medical care; three compared with other therapies.  
|                  | • Short-term mortality was significantly higher (OR = 6.16), but was significantly lower long term (OR = 0.76) for patients who had had surgery.  
|                  | • Patients with upper lobe-predominant emphysema and low baseline exercise capacity showed the best mortality outcomes in surgical patients. |
| Ahmad (2014)    | **Key points:**  
| Trends in procedure rates, predictors of in-hospital mortality for lung volume reduction surgery |  
|                  | • A total of 3,307 procedures were performed; the annual number fell from 550 to 200.  
|                  | • In-hospital mortality was 6.1%, unchanged over time.  
|                  | • Average days of hospital stay was nine days, unchanged over time.  
|                  | • 7.9% of patients required in-hospital tracheostomy.  
|                  | • Predictors of in-hospital mortality were age (older than age 65), presence of interstitial lung disease, and malnutrition (OR = 2.83, 2.81, and 2.74, respectively). |
| Zahid (2011)    | **Key points:**  
| Patterns of lung volume reduction surgery by patient characteristics |  
|                  | • Systematic review of seven studies comparing patients with emphysema undergoing lung volume reduction surgery or medical treatment.  
|                  | • Patients who had had surgery had higher quality of life scores (45.3 versus 27.5, P < 0.001).  
|                  | • Patients who had had surgery had improved maximum ventilation (32.8 L/min versus 29.6 L/min, P = 0.001).  
|                  | • Patients who had had surgery had lower exacerbation rate/person-year (0.27% versus 0.37%, P = 0.0005).  
|                  | • Mortality for the surgical group, higher than the medical group soon after surgery, equaled the medical group at three years (P = 0.15) and was lower after four years (P = 0.06).  
|                  | • Surgery most reduced probability of death in patients with upper-lobe-predominant disease and low exercise capacity (0.36 versus 0.54, P = 0.003).  
|                  | • Surgery most reduced probability of death in patients with non-upper-lobe disease (0.38
versus 0.45, \( P = 0.03 \) or upper-lobe-disease with high exercise capacity (0.33 versus 0.38, \( P = 0.32 \)).

- Five studies other than the National Emphysema Treatment Trial found that surgery was associated with greater six-minute walking distances (433 m versus 300 m, \( P < 0.002 \)), improved total lung capacity (18.8\% versus 7.9\% predicted, \( P < 0.02 \)), and quality of life scores (47 versus 23.2, \( P < 0.05 \)).

**Key points:**

- Results of landmark National Emphysema Treatment Trial.
- Patients with emphysema, surgery compared with medical treatment.
- Patients included those with a forced expiratory volume in one second < 20\% of their predicted value and either a homogeneous distribution of emphysema on computed tomography or a carbon monoxide diffusing capacity < 20\% of their predicted value.
- Patients who had had surgery had a 16\% 30-day mortality rate after surgery versus no deaths after medical treatment, \( P < 0.001 \).
- Patients who survived surgery had superior distance walked in six minutes (\( P = 0.03 \)).
- Patients who survived surgery had greater forced expiratory volume (\( P < 0.001 \)).
- Two groups had similar health-related quality of life.

### References

**Professional society guidelines/other:**


Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of chronic obstructive pulmonary disease (COPD). Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); March 2011.


U.S. Centers for Medicare & Medicaid Services (CMS). Decision memo on lung volume reduction surgery (CAG-001115R). Baltimore MD: CMS, August 20, 2003. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=96&ver=7&NcaName=Lung+Volume+Reduction+Surgery&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNC%7CME%7CMED%7CSTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=Lung+Volume+Reduction+Surgery&KeyWordLookUp=Doc&KeyWordSearchType=And&kq=true&bc=IAAAABAAIAAA&. Accessed January 4, 2018.

Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

Lung Volume Reduction Surgery (Reduction Pneumoplasty) (240.1). Effective November 17, 2005. [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=119&ncdver=3&NCAId=96&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lung+volume+reduction+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAQAAAA&. Accessed January 5, 2018.](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=119&ncdver=3&NCAId=96&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lung+volume+reduction+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAQAAAA&)

**Local Coverage Determinations (LCDs):**

Lung Volume Reduction Surgery (L34013). Effective October 1, 2015. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34013&ver=4&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lung+volume+reduction+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAQAAAA&. Accessed January 5, 2018.](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34013&ver=4&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=lung+volume+reduction+surgery&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAQAAAA&)

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>32141</td>
<td>Thoracotomy; with resection-plication of bullae, includes any pleural procedure when performed</td>
<td></td>
</tr>
<tr>
<td>32491</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>32672</td>
<td>Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>J43 – J43.9</td>
<td>Emphysema</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>