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<b>Preauthorization</b>	No	<b>Review Dates:</b> 02/07, 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

**Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With upper-lobe emphysema</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Lung volume reduction surgery</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Medical management</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Overall survival</li> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Treatment-related mortality</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With non-upper-lobe emphysema</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Lung volume reduction surgery</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Medical management</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Overall survival</li> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Treatment-related mortality</li> </ul>

### 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.

### SUMMARY OF EVIDENCE

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

bution of emphysema. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

## POLICY

Lung volume reduction surgery as a treatment for emphysema may be considered **medically necessary** in patients who meet ALL of the following criteria\*:

- Predominantly upper lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)
- Forced expiratory volume in one second (FEV<sub>1</sub>):
  - For patients who are younger than 70 years of age the FEV<sub>1</sub> must be no more than 45% of the predicted value
  - For patients who are 70 years of age or older the FEV<sub>1</sub> must be no more than 45% of the predicted value and 15% or more of the predicted value.
- Marked restriction in activities of daily living despite maximal medical therapy
- Age younger than 75 years
- Acceptable nutrition status (i.e., 70% to 130% of ideal body weight)
- Ability to participate in a vigorous pulmonary rehabilitation program
- No coexisting major medical problems that would significantly increase operative risk
- Willingness to undertake risk of morbidity and mortality associated with lung volume reduction surgery
- Abstinence from cigarette smoking for at least four months.

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

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

## POLICY GUIDELINES

The following additional criteria, also from the NETT trial, may further refine selection of a patient who is a candidate for lung volume reduction surgery (LVRS):

- Arterial partial pressure of oxygen on room air of 45 mm Hg or more (30 mm Hg or more at elevations of 5,000 feet [1524 meters] or higher)
- Arterial partial pressure of carbon dioxide 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 [1524 meters] or higher)

- Post-rehabilitation six-minute walk distance of at least 140 meters, and able to complete three minutes of unloaded pedaling in exercise tolerance test.

## MEDICARE ADVANTAGE

For Medicare Advantage, Lung Volume Reduction Surgery (LVRS) is **medically necessary** when:

1. The patient satisfies all the criteria outlined below:

Assessment	Criteria
History and physical examination	Consistent with emphysema
	BMI, $\leq 31.1 \text{ kg/m}^2$ (men) or $\leq 32.3 \text{ kg/m}^2$ (women)
	Stable with $\leq 20 \text{ mg}$ prednisone (or equivalent) qd
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second ( $\text{FEV}_1$ ) $\leq 45\%$ predicted $\geq 15\%$ predicted if age $\geq 70$ years
	Total lung capacity (TLC) $\geq 100\%$ predicted post-bronchodilator
	Residual volume (RV) $\geq 150\%$ predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	$\text{PCO}_2, \leq 60 \text{ mm Hg}$ ( $\text{PCO}_2, \leq 55 \text{ mm Hg}$ if one mile above sea level)
	$\text{PO}_2, \geq 45 \text{ mm Hg}$ on room air ( $\text{PO}_2, \geq 30 \text{ mm Hg}$ if one mile above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (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 EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation six-min. walk of $\geq 140 \text{ m}$ ; able to complete three min. unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level $\leq 13.7 \text{ ng/mL}$ (or arterial carboxyhemoglobin $\leq 2.5\%$ if using nicotine products)
	Non-smoking for four months prior to 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

2. In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity (see Medicare Advantage Policy Guidelines);

3. Also, LVRS is **medically necessary** only when performed at facilities that are Medicare approved facilities. (See Medicare Advantage Policy Guidelines).

LVRS is **not medically necessary** in any of the following clinical circumstances:

1. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;
2. The disease is unsuitable for LVRS;

3. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery (see Medicare Advantage Policy Guidelines);
4. The patient presents with FEV1  $\leq$  20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of less than or equal to 20% of predicted value (high-risk group identified October 2001 by the NETT); or
5. The patient satisfies the criteria outlined above in section 1 (of the medically necessary statement) and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

All other indications for LVRS are **investigational**.

### MEDICARE ADVANTAGE POLICY GUIDELINES

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing five or 10 watt/minute ramp on 30% oxygen after three minutes of unloaded pedaling.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Volume-Reduction-Surgery-LVRS.html>.

The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery. The program must include a six- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of two hours. It must also include at least six, and no more than 10, postoperative sessions, each lasting a minimum of two hours, within eight to nine weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

### BACKGROUND

#### EMPHYSEMA

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

obstruction related to chronic obstructive pulmonary disease is characterized by the reduced ratio of forced expiratory volume in one second/forced vital capacity and reduction in forced expiratory volume in one second correlates with long-term mortality risk.<sup>1</sup>

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

### 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.

### RELATED PROTOCOL

Outpatient Pulmonary Rehabilitation

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

### REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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