Criteria for Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Lung Volume Reduction Surgery (Reduction Pneumoplasty) (240.1)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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For Non-Medicare Members

Medical necessity review is no longer required for this service.

Background

Lung Volume Reduction Surgery (LVRS) is a general term that includes several surgical techniques used to treat chronic obstructive lung disease (COPD) due to emphysema. LVRS and similar surgical procedures are based on the premise that patients with severe emphysema have lungs that have become too large relative to their chest size. In LVRS, 20-30% of a patient's lungs are removed. Alternatives to surgery (medical management) include smoking cessation interventions, bronchodilators, anti-inflammatory agents, oxygen, mucolytic drugs, antibiotics, pulmonary exercise rehabilitation and α1-antitrypsin replacement therapy in deficient patients.

LVRS was first reported in 1957, but lack of objective evidence of benefit and an operative mortality rate of 18% prevented the procedure from becoming accepted at that time. Renewed interest in the procedure was generated by the work of Cooper and co-workers who began performing LVRS in 1993 with no operative mortality in their initial report; their first peer-reviewed manuscript on LVRS was published in 1995. Also in 1995, staff for the US Health Care Financing Administration (HCFA), decided that there was insufficient evidence about the effectiveness of LVRS to have this procedure covered by Medicare. Instead, HCFA decided to fund a randomized controlled trial, the National Emphysema Treatment Trial or NETT.

MTAC initially reviewed LVRS in 2000, before completion of the NETT. Results of the NETT were published in May, 2003 and will be evaluated in the current review. The LVRS technique considered in this review is the procedure included in the NETT, the bilateral stapled procedure.

Medical Technology Assessment Committee (MTAC)

Lung Volume Reduction Surgery in the treatment of Chronic Obstructive Lung Disease

06/14/2000: MTAC REVIEW

Evidence Conclusion: Recent studies do not provide sufficient evidence to make conclusions about the efficacy of LVRS in improving lung function and survival in patients with COPD, due to emphysema. There is still a lack of evidence about the effectiveness of LVRS compared to medical management. In addition, in the published studies
the issue of LVRS efficacy is confounded by pulmonary rehabilitation. Most surgical patients also received rehabilitation; without a control group of patients who did not receive surgery, it is not possible to know whether intervention effects were due to LVRS or rehabilitation. The one RCT (Criner et al., 1999) that purported to examine LVRS compared to medical treatment (in this case, pulmonary rehabilitation) had serious flaws. The two intervention groups were not compared in analysis, patients in the LVRS group did not all receive the same intervention (some had 3 additional months of rehabilitation), and the sample size was small (total n=37). The Meyers et al. (1998) study gathered information from patients who were and were not approved by Medicare to receive LVRS. The Meyers study provides weak evidence of improved outcomes with LVRS; threats to validity include selection bias (patients were not randomized and could choose surgery if they could afford it), the lack of consistent medical management in the comparison group and the small number of patients who did not receive surgery (n=22).

**Articles:** The literature search yielded 97 articles. Articles were selected based on study type and relevancy to the purpose of this review. Articles were excluded that were reviews or commentaries, examined technical aspects of the LVRS procedure, or were case series with small samples sizes (<50). Also excluded were articles that compared laser vs. stapled LVRS, or unilateral vs. bilateral LVRS because this review was limited to bilateral stapled LVRS. **Articles selected for critical appraisal include:** An RCT comparing LVRS to pulmonary rehabilitation: Criner, GJ, Cordova, FC, Furukawa, S, Kuzma, AM, Travaline, JM, Leyenson, V, O’Brian, GM. Prospective randomized trial comparing bilateral lung volume reduction surgery to pulmonary rehabilitation in severe chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1999; 160: 2018-2027. See Evidence Table. A meta-analysis of case series studies: Young, J, Fry-Smith, A, Hyde, C. Lung volume reduction surgery (LVRS) for chronic obstructive pulmonary disease (COPD) with underlying severe emphysema. Thorax 1999; 54: 779-89. See Evidence Table. A cohort study comparing LVRS candidates who did and did not receive LVRS due to changes in Medicare coverage policy: Meyers, BF, Yusen, RD, Lefrak, SS, Patterson, GA, Pohl, MS, Richardson, VJ, Cooper, JD. Outcome of Medicare patients with emphysema selected for, but denied, a lung volume reduction operation. Ann Thorac Surg 1998; 66: 331-6. See Evidence Table. A large case series study of bilateral, staple LVRS with longer-term follow-up: Brenner, M, McKenna, RJ, Chen, JC, Osann, K, Powell, L, Gelb, AF, Fischel, RJ, Wilson, AF. Survival following lung volume reduction surgery for emphysema. Chest 1999; 115: 390-396. See Evidence Table.

The use of Lung Volume Reductions Surgery in the treatment of Chronic Obstructive Lung Disease due to emphysema does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**04/14/2004: MTAC REVIEW**

**Lung Volume Reductions Surgery in the treatment of Chronic Obstructive Lung Disease**

**Evidence Conclusion:** The best evidence is from the National Emphysema Treatment Trial (NETT), a large randomized controlled trial comparing LVRS in addition to pulmonary rehabilitation and medical management to pulmonary rehabilitation and medical management alone. The main findings of the study were that there was no overall difference in mortality between the two groups, but there was a greater improvement in exercise capacity at 2 years with LVRS than medical treatment. There were also better outcomes in health-related quality of life, distance walked in 6 minutes, percentage of the predicted value for FEV₁, and degree of dyspnea in the LVRS group (with high-risk patients excluded). A limitation of the study design was that it was not blinded which could introduce bias, especially for subjective outcomes such as quality of life. The authors defined four subgroups by location of emphysema and exercise capacity. Compared to the medical treatment group, there was a lower mortality rate in patients with predominantly upper lobe-emphysema and low-exercise capacity who received LVRS, and a higher mortality rate in patients with predominantly non-upper lobe emphysema who had high exercise capacity. There were no significant differences in mortality in the other two sub-groups. These sub-group findings can be considered preliminary and would need to be confirmed in additional studies.

**Articles:** The search yielded 183 articles, many of which were reviews, editorials or commentaries. There were three randomized controlled trials; the National Emphysema Treatment Trial with more than 1200 participants and two smaller RCTs, each with fewer than 100 individuals. The NETT was critically appraised. National Emphysema Treatment Trial Research Group. A randomized trial comparing lung-volume-reduction surgery with medical therapy for severe emphysema. N Engl J Med 2003; 348: 2059-2073.(Methodological information taken from earlier NETT publications) See Evidence Table.

The use of Lung Volume Reductions Surgery in the treatment of Chronic Obstructive Lung Disease due to emphysema does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

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<th>Revision History</th>
<th>Description</th>
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**Codes**

CPT: 32491
HCPCS: G0302; G0303; G0304; G0305