CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 3 **Date: NOVEMBER 4, 2003**

CHANGE REQUEST 2688

I. SUMMARY OF CHANGES: Medicare coverage for lung volume reduction surgery (LVRS) is expanded to include patients who are: (1) Non high-risk and present with severe, upper-lobe emphysema; or, (2) Non high-risk and present with severe, non upper-lobe emphysema with low exercise capacity. In addition, these patients must satisfy **all** of the requirements as outlined in §240.1 of the Medicare National Coverage Determinations (NCD) Manual. (**NOTE:** New G codes describing pre- and post-operative LVRS services to be effective January 1, 2004, can be accessed in the OPPS Final Rule to be published in the **Federal Register**.)

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004
***IMPLEMENTATION DATE: January 5, 2004**
****M+C IMPLEMENTATION DATE: April 5, 2004**

(Corresponding one-time notification contains billings instructions for M+C providers.)**

(This revision to §240.1 of Pub. 100-03 is an NCD. NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED –

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/240.1/Lung Volume Reduction Surgery (Reduction Pneumoplasty)

III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification

240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)

(Rev. 3, 11-04-03)

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand, and thus, improve respiratory function.

A. Covered Indications

Medicare-covered LVRS approaches are limited to bilateral excision of a damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

1. *National Emphysema Treatment Trial (NETT) participants (effective for services performed on or after August 11, 1997):*

   Medicare provides coverage to those beneficiaries who are participating in the NETT trial for all services integral to the study and for which the Medicare statute does not prohibit coverage.

2. *Medicare will only consider LVRS reasonable and necessary when all of the following requirements are met (effective for services performed on or after January 1, 2004):*

   a. *The patient satisfies all the criteria outlined below:*

Assessment	***Criteria***
History and physical examination	*Consistent with emphysema*
	BMI, ≤ 31.1 kg/m^2 (men) or ≤ 32.3 kg/m^2 (women)
	Stable with ≤20 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 (FEV_1) ≤ 45% predicted (≥ 15% predicted if age ≥70 years)*
	Total lung capacity (TLC) ≥100% predicted post-bronchodilator
	Residual volume (RV) ≥150% predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	*PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if 1-mile above sea level)*
	PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 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; 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 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)*
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 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*

b. *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.*

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 5 or 10 watt/minute ramp on 30% oxygen after 3 minutes of unloaded pedaling.

c. *The surgery must be performed at facilities that were identified by the National Heart, Lung, and Blood Institute to meet the thresholds for participation in the NETT,* ***and*** *at sites that have been approved by Medicare as lung transplant facilities. These facilities are listed on our Web site at www.cms.hhs.gov/coverage/lvrsfacility.pdf. The CMS is currently working to develop accreditation standards for facilities to perform LVRS and when implemented, will consider LVRS to be reasonable and necessary only at accredited facilities.*

d. 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 6- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of 2 hours. It must also include at least 6, and no more than 10, postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 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.

B. Noncovered Indications

*1. LVRS is not covered in **any** of the following clinical circumstances:*

a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;

b. The disease is unsuitable for LVRS;

c. 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;

*d. The patient presents with $FEV_1 \leq 20\%$ of predicted value, and either homogeneous distribution of emphysema on CT scan**, or** carbon monoxide diffusing capacity of $\leq 20\%$ of predicted value (high-risk group identified October 2001 by the NETT); or*

e. The patient satisfies the criteria outlined above in section 2(a), 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).

2. All other indications for LVRS not otherwise specified remain noncovered.

(This NCD last reviewed October 2003.)