



**Subject:** *Lung Volume Reduction Surgery*

**Number:** *200309-0001*

Effective date: 09/05/2003

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**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

**Overview**

Lung volume reduction surgery (LVRS) is a surgical treatment for patients with severe emphysema. The theory underlying LVRS is to reduce airway obstruction by improving lung elastic recoil and by providing more effective diaphragmatic function by reducing lung hyperinflation. LVRS is performed by excision of the affected lung tissue. The candidate for LVRS should have severe emphysema, disabling dyspnea, and evidence of severe air trapping.

This policy is primarily based on the Centers for Medicare & Medicaid Services (CMS) determinations and the National Emphysema Treatment Trial (NETT).

**Policy and criteria**

**NOTE:** These services require prior authorization by the plan medical director.

**When services are covered:**

We cover **bilateral LVRS** for **non-high risk** patients who satisfy the inclusion and exclusion criteria outlined in the NETT protocol **and** have:

- **Severe upper lobe emphysema;** or
- **Severe non-upper lobe emphysema with low exercise capacity.**

In addition, we require that the procedure be performed at:

- An in-network facility certified by CMS for lung transplants for the **commercial plan** member,  
OR
- A contracted facility certified by CMS for lung transplants for the **Fallon Senior Plan™** member.

**Covered services:**

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

***When services are not covered:***

We **do not cover** services when the above criteria are not met.

We **do not cover** LVRS under the following circumstances because it has not been scientifically proven to be effective:

- For high-risk patients with severe emphysema. A high-risk patient is one who has:
  - A forced expiratory volume in the first second (FEV<sub>1</sub>) that is 20% or less of their predicted value, **and**
  - Either homogeneous distribution of emphysema on CT scan *or* low carbon monoxide diffusing capacity (D<sub>L</sub>CO) that is 20% or less of their predicted value
- For non-high risk patients who satisfy the inclusion and exclusion criteria outlined in the NETT protocol and have severe non-upper lobe emphysema with high exercise capacity.
- Any other indication for LVRS.

We **do not cover unilateral** LVRS for emphysema patients, because there are insufficient data to suggest that patients will experience clinical benefit.

We do not cover **thoroscopic laser ablation** or **bullectomy** as they are investigational in the treatment of members with emphysema. The benefit of this procedure has not been conclusively demonstrated.

**Absolute contraindications:**

- We **do not cover** LVRS for a member who has smoked within four months.

**Relative contraindications:**

- We may not cover LVRS for a member who has smoked within six months.

**FCHP products to which this policy applies:**

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Major Medical
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home

Medicare plan – *reminder* to refer to CMS for policy and criteria

**References**

1. U.S. Department of Health and Human Services, Agency for Healthcare Policy and Research. Lung-volume reduction surgery for end-stage chronic obstructive pulmonary disease. AHCPR Health Technology Assessment No. 10. Pub. No. AHCPR 96-0062. Bethesda, MD: AHCPR, September 1996.
2. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) [Web site]. National Coverage Analysis (NCA). Lung volume reduction surgery (#CAG-00115R).
3. U.S. Department of Health and Human Services, Health Care Financing Administration. Lung volume reduction surgery (reduction pneumoplasty, also called lung shaving or lung contouring), unilateral or bilateral by open or thoroscopic approach for the treatment of emphysema and chronic obstructive pulmonary disease - not generally covered. Medicare Coverage Issues Manual §35-93. HCFA Pub. 6. Baltimore, MD: HCFA, 2000.
4. National Emphysema Treatment Trial Research Group. Patients at high risk of death after lung-volume-reduction surgery. *N Engl J Med.* 2001;345(15):1075-1083.
5. 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(21):2059-2073.
6. Hayes, Inc.
  - In the News. *Medicare to Cover Lung Volume Reduction Surgery for Selected Patients at Approved Facilities.* Volume VI, Number 8: August 2003.

- Clinical Studies. *Lung Volume Reduction Surgery Does Not Prolong Survival*. Volume VI, Number 6: June 2003.
- Clinical Studies. *LVRS Dangerous for Patients with Severe Emphysema*. Volume III, Number 8: August 2001.
- Clinical Studies. *Benefits and Risks of LVRS Remain Unclear*. Volume III, Number 8: August 2000.
- Report. *Lung Volume Reduction Surgery for Chronic Obstructive Pulmonary Disease*. February 1998. Search updated June 2003

**Mandated benefit/Regulatory issues**

- Ø Federal
- Ø Commonwealth of Massachusetts
- ⊕ Medicare – National Policy
- ⊕ Medicare – Local Medical Review Policy
- Ø Not applicable

**Committee review dates:**

**Accepted by Technology Assessment Committee:** 11/2003

Approved by:	<i>Signature on file</i>	<i>9/09/2003</i>
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