



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Lung Volume Reduction Surgery (LVRS)**

**Effective Date ..... 11/15/2010**  
**Next Review Date ..... 11/15/2012**  
**Coverage Policy Number ..... 0218**

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## Hyperlink to Related Coverage Policies

Alpha<sub>1</sub>-Proteinase Inhibitor (Human)  
(Aralast NP™, Aralast™, Prolastin®,  
Zemaira®)  
Lung and Heart-Lung Transplantation  
Oxygen for Home Use  
Pulmonary Rehabilitation

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA covers lung volume reduction surgery (LVRS) for individuals with severe emphysema when ALL of the following criteria are met:**

- radiological evidence of bilateral upper-lobe (heterogeneous) emphysema
- smoking cessation for at least six months
- low functional capacity after pulmonary rehabilitation
- pulmonary function test results showing:
  - forced expiratory volume in one second (FEV<sub>1</sub>) ≤ 45% of predicted and, if age 70 or older, FEV<sub>1</sub> ≥15% of predicted value
  - post-bronchodilator total lung capacity (TLC) ≥100% of predicted and residual volume (RV) ≥ 150% of predicted value
- resting partial pressure of oxygen (P<sub>a</sub>O<sub>2</sub>) ≥45 mm Hg and resting partial pressure of carbon dioxide (P<sub>a</sub>CO<sub>2</sub>) ≤60 mm Hg on room air
- six-minute walk test > 140 meters
- cardiology clearance for the presence of ANY of the following:
  - unstable angina
  - left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram
  - LVEF < 45 %
  - nuclear cardiac scan indicates coronary artery disease (CAD) or ventricular dysfunction
  - arrhythmia with greater than five premature ventricular contractions (PVCs) per minute

- cardiac rhythm other than normal sinus rhythm (NSR)
- PVCs on electrocardiogram (EKG) at rest

**CIGNA does not cover LVRS for any other indication because it is considered experimental, investigational or unproven.**

**CIGNA does not cover bronchoscopic lung volume reduction procedures (e.g., bronchial valve placement, biologic lung volume reduction, bronchopulmonary fenestration) because they are considered experimental, investigational or unproven.**

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## General Background

Pulmonary emphysema is an irreversible condition characterized by progressively increasing dyspnea on exertion and eventually at lower levels of activity. The fine architecture and elasticity of the lungs are destroyed, resulting in obstruction of the airways, trapping of air, and difficulty exchanging oxygen. While there are many known causes of emphysema, including alpha-1-antitrypsin deficiency, cystic fibrosis, air pollution, occupational exposure, and bronchiectasis, the disease process generally results directly from tobacco abuse. The importance of smoking cessation is stressed as the single most effective way to reduce the risk of developing emphysema and stop its progression.

Medical therapy for COPD typically includes smoking cessation intervention, bronchodilators, anti-inflammatory agents, oxygen, mucolytic drugs, influenza and pneumococcal vaccinations, antibiotics, pulmonary rehabilitation, and alpha-1-antitrypsin replacement therapy in patients who are deficient. Malnutrition is associated with a poor prognosis for patients with COPD, since it predisposes such patients to infections, as well as reducing respiratory muscle force, exercise tolerance and quality of life. Poor nutritional status can be modified through appropriate and efficacious diet therapy and monitoring (Fernandes and Bezerra, 2006). Long-term home oxygen use in hypoxemic patients has been proven to decrease mortality rates, and smoking cessation has been shown to slow the rate of progression of COPD. Surgical treatments available for severe emphysema that is unresponsive to medical therapy include bullectomy for patients with bullous lung disease, lung transplantation, and lung volume reduction surgery.

### Lung Volume Reduction Surgery (LVRS)

LVRS involves resecting emphysematous lung tissue, usually from both upper lobes. The procedure may be performed by video-assisted thoracic surgery (VATS) or by median sternotomy. The affected lung tissue is stapled, resected and removed from the chest cavity. Laser excision has been utilized in an attempt to decrease the rate of complication due to air leaks. The goal of the surgery is to reduce the overall volume of the lung by 20–30%, while preserving non-diseased tissue and the normal anatomical shape of the lung. The remaining lung tissue has enhanced recoil and improved gas-exchange properties, which are presumed mechanisms leading to improved survival, functional gains and symptomatic relief. Lung function is improved by reversing the adverse effects of hyperinflation and uneven ventilation, in turn, decreasing the work of breathing and improving alveolar gas exchange. LVRS is palliative, however, not curative; its objective is to improve functional status and quality of life.

### Literature Review

The evidence in the published peer-reviewed literature examining the safety and effectiveness of LVRS includes meta-analyses, technology assessments, RCTs, and observational studies (Tiong, et al., 2006; Berger, et al., 2005; National Institute for Clinical Excellence [NICE], 2005; Miller, et al., 2005; Goldstein, et al., 2003; Geddes, et al., 2000) with patient populations ranging from 93–1663. In general study results have demonstrated significant improvements in functional capacity with LVRS compared to medical therapy for advanced emphysema. Mortality rates have been reported to be higher after LVRS, ranging from 4%–10%.

The National Emphysema Treatment Trial (NETT) helped to define the subset of patients who might benefit the most from LVRS, as well as those patients who would be at the highest risk for the procedure. The NETT was a multicenter, randomized, controlled clinical trial (n=1218) that compared LVRS (n=608) to medical therapy (n=610) for severe emphysema. Selection criteria for the study included: FEV1  $\leq$ 45%, but  $\geq$ 15% for patients  $\geq$ 70 yrs; TLC  $\geq$ 100% predicted; RV  $\geq$ 150%; PaCO2  $\leq$ 60 mm Hg; PaO2  $\geq$ 45 mm Hg; six-minute walk test > 140

meters; body mass index (BMI)  $\leq 31.1$  for males and  $\leq 32.3$  for females; abstinence from smoking for at least six months and completion of the NETT pulmonary rehabilitation program. Exclusion criteria included the following (Fishman, et al., 2003):

- diffuse emphysema deemed unsuitable for LVRS
- pleural or interstitial disease precluding surgery
- pulmonary nodule requiring surgery
- previous sternotomy or lobectomy
- uncontrolled hypertension
- pulmonary hypertension
- LVEF  $< 45\%$  AND myocardial infarction or congestive heart failure within the previous six months
- cardiac dysrhythmias which might pose a risk during exercise testing
- oxygen requirement that exceeds six liters at rest to maintain saturation level at a minimum of 90%

Maximal functional capacity, pulmonary function as measured by FEV<sub>1</sub>, and quality of well-being were found to be higher in the surgical group. The results revealed no difference in overall mortality between the two groups after a mean follow-up observation period of 29 months. The risk of death during the first three months after randomization was higher in the surgical group than in the medical treatment group,

Researchers found that two characteristics helped predict if an individual participant would benefit from LVRS: whether the emphysema was concentrated in the upper lobes of the lungs and whether functional capacity was low or high. For those in the LVRS group, functional capacity was measured after medical therapy but before surgery. A functional capacity score  $\leq 25$  W for females or  $\leq 40$  W for males was considered low; a score  $> 25$  W for females or  $> 40$  W for males was considered high. The NETT suggested that the best predictors of postsurgical improvement are upper-lobe predominance emphysema and low postrehabilitation functional capacity, measured while breathing 30% inspiratory oxygen fraction on cycle ergometry.

Naunheim et al. (2006) presented an updated analysis of NETT data at a median follow-up of 4.3 years. The evidence for differential risk and benefit after LVRS in the four subgroups defined by baseline exercise capacity (i.e., low versus high) and distribution of emphysema (i.e., upper-lobe versus non-upper-lobe) persisted in this analysis. The following observations were reported:

1. For patients with predominantly upper-lobe emphysema and low postrehabilitation exercise capacity, the additional data confirmed the beneficial effects of LVRS. The survival advantage of the LVRS group over the medical treatment group that was previously demonstrated after a median of 2.4 years of follow-up ( $p=0.005$ ) was sustained in the longer follow-up period ( $p=0.01$ ). Long-term follow-up strongly supports the performance of LVRS in this subgroup that comprised 24% of the NETT population.
2. For patients with upper-lobe disease and high postrehabilitation exercise capacity, LVRS had no survival advantage or disadvantage. Patients in this subgroup (34% of all enrolled patients) who are looking primarily for symptomatic improvement may benefit from LVRS.
3. Patients with non-upper-lobe-predominant emphysema and low postrehabilitation exercise capacity had limited improvement in exercise capacity regardless of treatment. Survival was not found to be different between the LVRS and medical groups. Recommendations regarding LVRS in this subgroup are guarded because the primary benefit is improvement in HRQL, which appears to dissipate within three years after surgery.
4. For patients in the subgroup characterized by non-upper-lobe-predominant emphysema and high postrehabilitation maximum work, LVRS initially led to a higher mortality. Extended follow-up confirmed that these patients have little chance of functional or symptomatic improvement and, therefore, are poor candidates for LVRS.

The authors also noted that extended follow-up revealed a survival advantage with LVRS for the entire NETT population. It was concluded that the "effects of LVRS are durable, and it can be recommended for upper-lobe-predominant emphysema patients with low exercise capacity. LVRS should be considered for palliation in patients with upper-lobe emphysema and high exercise capacity" (Naunheim, et al., 2006).

### Bronchoscopic Lung Volume Reduction Procedures

Minimally invasive techniques to attain lung volume reduction without open thoracotomy are under investigation. Inclusion and exclusion criteria for bronchoscopic emphysema treatment strategies are similar to those used for LVRS. Bronchoscopic devices and techniques being evaluated include (Berger, et al., 2010):

- one-way bronchial valves inserted by fiberoptic bronchoscopy to promote atelectasis in the emphysematous lung (e.g., Endobronchial Valve [EBV], Emphasys Medical Inc., Redwood City, CA)
- deployment of a biodegradable gel into bronchi to collapse targeted hyperinflated pulmonary parenchyma and initiate an inflammatory response to selectively reduce the volume of treated lung (Biologic Lung Volume Reduction [BioLVR], Aeris Therapeutics, Inc. Woburn, MA)
- bronchopulmonary fenestrations to enhance expiratory flow (e.g., Airway Bypass Tracts [ABT], Broncus Inc. Mountain View, CA)

None of these devices have been approved by the U.S. Food and Drug Administration (FDA) for use in the U.S. for any indication

**Literature Review:** The evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of bronchoscopic lung volume reduction procedures for severe emphysema consists of few observational studies with small patient populations (range 13–50) and short-term follow-up (Refaely, et al., 2010; Criner, et al., 2009; Wood, et al., 2007; Venuta, et al., 2005). Preliminary results suggest that bronchoscopic approaches may be associated with lower mortality and morbidity than LVRS, but with decreased effectiveness. Larger, well designed studies are needed to demonstrate the efficacy of these procedures for the treatment of advanced emphysema. There is insufficient evidence in the published peer-reviewed literature to support any of the bronchoscopic lung volume reduction procedures for this condition.

### Professional Societies/Organizations

The 2004 ATS and European Respiratory Society (ERS) guidelines for the diagnosis and management of COPD in 2004. According to this document, “LVRS may result in improved spirometry, lung volumes, exercise capacity, dyspnea, HRQL, and possibly survival in highly selected patients” (Celli and McNee, 2004).

The Centers for Medicare & Medicaid Services (CMS) revised its policy on LVRS in 2003. This policy states that patients who are suitable for LVRS must be non-high-risk as defined by NETT and present with severe upper-lobe predominant emphysema, or severe non-upper-lobe emphysema with low exercise capacity. In addition, patients must satisfy all of the following criteria (CMS, 2003):

Assessment	Criteria
History and physical examination	Consistent with emphysema
	Body mass index (BMI), $\leq 31.1$ kg/m (men) or $\leq 32.3$ kg/m (women)
	Stable with $\leq 20$ mg prednisone (or equivalent) once per day
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV) $\leq 45\%$ 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)	$PCO_2, \leq 60$ mm Hg ( $PCO_2, \leq 55$ mm Hg if one mile above sea level)

	PO <sub>2</sub> , ≥ 45 mm Hg on room air (PO <sub>2</sub> , ≥ 30 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 (> five 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-minute walk of ≥ 140 meters (m); able to complete three-minute 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 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

The CMS states that patients with the following clinical circumstances are not candidates for LVRS:

- high risk for perioperative morbidity and/or mortality
- disease that is unsuitable for LVRS
- medical conditions or other circumstances that render the patient unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery
- FEV<sub>1</sub> ≤ 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or DLCO ≤ 20% of predicted value (i.e., high-risk group identified by the NETT)
- severe, non-upper lobe emphysema with high exercise capacity (i.e., maximum workload > 25 W (Watts) for women and > 40 W for men, cycling for three minutes while breathing 30% oxygen)

The American Thoracic Society's (ATS) position statement of May 1996 recommends that LVRS be performed in institutions where a multidisciplinary team, including pulmonologists and thoracic surgeons and a high level of diagnostic and surgical expertise, are available. Patients undergoing LVRS should have advanced emphysema with disabling dyspnea and evidence of severe air trapping. Advanced age (i.e., > age 75) and significant comorbid illness have been considered contraindications to LVRS (ATS, 1996).

### Summary

The peer-reviewed literature contains sufficient evidence to conclude that LVRS is indicated for the treatment of patients with end-stage, severe bilateral, upper-lobe emphysema and disabling dyspnea with low functional capacity after a course of pulmonary rehabilitation. LVRS has been shown to produce significant improvement in pulmonary function, dyspnea, functional capacity, and general health-related quality of life (HRQL) for this subset of individuals. LVRS is associated with increased survival and decreased mortality rates for those with predominantly upper-lobe disease and low functional capacity in comparison to those with non-upper-lobe disease.

The evidence in the peer-reviewed scientific literature does not support the safety and effectiveness of bronchoscopic lung volume reduction procedures for any indication, including the treatment of emphysema.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®*</sup> Codes	Description
32491	Removal of lung, other than total pneumonectomy; excision-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, with or without any pleural procedure

ICD-9-CM Diagnosis Codes	Description
492.0	Emphysematous bleb
492.8	Other emphysema

**Experimental/Investigational/Unproven/Not Covered:**

CPT <sup>®*</sup> Codes	Description
31899 <sup>†</sup>	Unlisted procedure, trachea, bronchi

<sup>†</sup>**Note:** Experimental/Investigational/Unproven/Not Covered when used to report bronchoscopic lung volume reduction procedures

ICD-9-CM Diagnosis Codes	Description
	All other codes

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2010 American Medical Association: Chicago, IL.

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	11/15/2007	0218	Lung Volume Reduction Surgery (LVRS)
Great-West Healthcare	10/26/2006	96.243.04	Lung Volume Reduction Surgery

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