MEDICAL POLICY

Excellus

SUBJECT: LUNG VOLUME REDUCTION SURGERY	**EFFECTIVE DATE: 09/16/99** **REVISED DATE: 12/21/00, 12/20/01, 11/21/02, 10/15/03, 08/19/04, 06/16/05, 05/18/06, 03/15/07, 02/21/08** **ARCHIVED DATE: 12/18/08** **EDITED DATE: 11/19/09, 11/18/10, 10/20/11, 11/15/12, 11/21/13**
POLICY NUMBER: 7.01.14 **CATEGORY: Technology Assessment**	**PAGE: 1 OF: 6**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, lung volume reduction surgery as a treatment for patients with severe emphysema is considered **medically appropriate** when ALL of the following criteria are met:
   A. Age younger than 75 years;
   B. Presence of severe obstruction-after bronchodilator - FEV_1 between 15% and 45% of predicted;
   C. Presence of hyperinflation - total lung capacity greater than or equal to 100% of predicted or residual volume greater than or equal to 150% of predicted;
   D. No evidence of saccular bronchiectasis;
   E. Moderate to severe decrease in the health-related quality of life;
   F. Absence of severe pulmonary hypertension - mean pulmonary artery pressure generally less than 35mm Hg or systolic pulmonary artery pressure generally less than 45mm Hg;
   G. Preserved alveolar ventilation - $PaCO_2$ less than or equal to 60 mm Hg;
   H. Adequate rehabilitation potential - completion of a 6-week pulmonary-rehabilitation program;
   I. Compliance with prescribed medical regimen including smoking cessation greater than four months; and
   J. Disease heterogeneity with predominantly upper lobe emphysema as assessed by CT Scan with target areas (minimally perfused lung with marked parenchymal destruction) and reserve zones (well perfused lung without marked parenchymal destruction) or carbon monoxide diffusing capacity at least 20% of predicted value.

II. Based upon our criteria and review of the peer-reviewed literature LVRS, will be considered **not medically appropriate** with *any* of the following:
   A. Significant comorbidity – non respiratory illness with an expected 5 year mortality greater than 50% (e.g., malignancy, organ failure);
   B. End-stage cardiopulmonary impairment (e.g., 6 minute walk less than 400 feet, ventilator dependence);
   C. Inability to cope with the psychological stress of the evaluation process and treatment (e.g., severe depression, anxiety disorder);
   D. Active chemical dependence during the past 12 months; or
   E. Conditions associated with increased surgical risk or in which benefit from LVRS is not anticipated (e.g., patients with predominantly non-upper-lobe emphysema and a high exercise capacity; severe coronary artery disease; previous thoracic operation or pleurodesis; chest wall deformity; corticosteroid dependence or corticosteroid-responsive hyperreactive airways disease, or both; airways disease with copious purulent secretions or frequent lower respiratory tract infections, or both; regular tobacco use within the past 4 months; or any tobacco use within the past 3 months).

III. Based upon our criteria and review of the peer-reviewed literature, bronchoscopic lung-volume reduction procedures have not been proven to be medically effective and are considered **investigational**.

Refer to Corporate Medical Policy #8.01.15 regarding Pulmonary Rehabilitation.

POLICY GUIDELINES:

I. LVRS should not be performed on patients with the following diagnoses: chronic bronchitis, asthma, restrictive lung diseases, pulmonary hypertension, or disease of the heart, kidneys or liver.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Lung volume reduction surgery (LVRS) is a treatment for patients with severe chronic obstructive pulmonary disease from emphysema involving the excision of peripheral emphysematous lung tissue, generally from both upper lobes. The precise mechanism of clinical improvement has not been firmly established. It is believed that LVRS reduces airway obstruction by improving lung elastic recoil and by providing more effective diaphragmatic function by reducing lung hyperinflation. The treatment is palliative, not curative, and is intended to relieve dyspnea (shortness of breath) and improve functional status and quality of life in selected patients with severe emphysema. Persons with emphysema eventually show progress of their disease and develop severe dyspnea, recurrent infection, hypoxia and right heart failure. Cessation of smoking and elimination of environmental irritants slows disease progression.

Recently, there has been some interest in developing less invasive methods and devices to achieve some of the same effects as LVRS. Device designs discussed in the literature include the use of fibrin-based glue, occluded stents, medical adhesives, and intrabronchial valves. These devices are designed to be placed using a bronchoscope. The goal of these procedures is to duplicate the benefit of LVRS without the trauma, risks, and extended recovery of median sternotomy or video-assisted thoracoscopic surgery approaches.

RATIONALE:

There is sufficient data published in the medical literature to conclude that lung volume reduction surgery improves health outcomes for carefully selected patients with severe obstructive lung disease. Improved health outcomes have been achieved outside the investigational setting.

Findings of the National Emphysema Treatment Trial (NETT) published in 2003 indicate that persons with predominantly non-upper-lobe emphysema and a high exercise capacity have been found to have higher mortality from LVRS than from medical therapy alone. There is a survival advantage for patients with both predominantly upper lobe emphysema and low baseline exercise capacity.

An updated analysis of the NETT data (Naunheim, et al. 2006) at a median follow-up of 4.3 years, determined that the comparisons of survival and functional improvement were consistent with initial results for the four clinical subgroups of non-high-risk patients defined by upper-lobe predominance and exercise capacity. The longer follow up period confirmed the continued beneficial effects of LVRS over medical treatment only for upper-lobe patients with low exercise capacity for improved survival, exercise tolerance and symptoms. In addition, the study determined that although upper-lobe-predominant and high-exercise-capacity LVRS patients obtained no survival advantage from LVRS, they were likely to improve exercise capacity and health-related quality of life. The authors concluded, "The effects of LVRS are durable, and it can be recommended for upper-lobe-predominant emphysema patients with low exercise capacity and should be considered for palliation in patients with upper-lobe emphysema and high exercise capacity".

In a Cochrane review, Tiong et al. (2007) analyzed eight RCTs (n=1663) that studied the safety and efficacy of LVRS in patients with diffuse emphysema. The NETT accounted for 73% of the subjects in this review. Studies included a variety of approaches and techniques (e.g., VATS, median sternotomy with unilateral or bilateral stapling). Outcome measures included postoperative complications and mortality, lung function parameters, and disability and health status. Control

groups consisted of either optimal medical follow-up, or different surgical techniques. In many of the studies, a prerequisite for study entry was the completion of a course of pulmonary rehabilitation. The 90-day mortality data primarily from the NETT indicated that death was more likely with LVRS, regardless of risk status identified. However, improvements in lung function, quality of life and exercise capacity were more likely with LVRS than with usual medical follow-up. The authors concluded that LVRS can only be recommended in patients who have completed a course of pulmonary rehabilitation, and whose candidature for surgery has been established through high resolution CT findings.

The American Thoracic Society (ATS) conducted a systematic review of the evidence in 2004 and proposed that the following factors are associated with better outcomes from LVRS: heterogeneous emphysema, thoracic hyperinflation, and low functional capacity.

There is insufficient evidence in published literature to conclude that bronchoscopic procedures such as the use of fibrin-based glue, occluded stents, medical adhesives, or intrabronchial valves achieve some of the same effects as LVRS to improve the functional status of patients with emphysema. In theory, the devices may function by causing a portion of the lung to collapse, thus reducing the total lung volume or by reducing the volume of dead space in the lung. A multicenter, randomized trial (Endobronchial Valve for Emphysema Palliation Trial ([VENT]) to assess the safety and efficacy of the Emphasys Endobronchial Valve (EBV) and procedure (with pulmonary rehabilitation) compared to optimal medical management (with pulmonary rehabilitation) in patients with heterogeneous emphysema is currently ongoing.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	32491	Removal of lung, other than total pneumonectomy; resection- plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure when performed
	32672	Thorascopy, surgical; with resection –plication for emphysematous lung (bullous or non0bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed

HCPCS:	G0302	Preoperative pulmonary surgery services for preparation for LVRS, complete course of services to include a minimum or 16 days of services
	G0303	Preoperative pulmonary services for preparation for LVRS, 10 to15 days of services
	G0304	Preoperative pulmonary services for preparation for LVRS, 1 to 9 days
	G0305	Post discharge pulmonary surgery services after LVRS, minimum of 6 days of services
ICD9:	492	Emphysema
	492.8	Other emphysema
	518.1	Interstitial emphysema

ICD10:

J43.0-J43.9	Emphysema (code range)
J44.0-J44.9	Chronic obstructive pulmonary disease (used for emphysema with chronic obstructive bronchitis) (code range)
J98.2	Interstitial emphysema

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* key article

KEY WORDS:

Emphysema, Lung volume, Pneumonectomy, LVRS.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for lung volume reduction surgery. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=119&ncdver=3&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&