**Prior Authorization Review**  
Panel MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policy Number:</strong> 0160</td>
<td><strong>Effective Date:</strong> 10/17/2018</td>
</tr>
<tr>
<td><strong>Policy Name:</strong> Lung Volume Reduction Surgery</td>
<td><strong>Revision Date:</strong> 10/17/2018</td>
</tr>
</tbody>
</table>

**Type of Submission – Check all that apply:**
- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0160 Lung Volume Reduction Surgery**

**Revision History since last PARP submission:**
10/17/2018 - This CPB has been revised to state that Food and Drug Administration (FDA)-approved endobronchial valve (e.g., the Zephyr Valve System) is considered medically necessary for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.
02/07/2019 – Next tentative scheduled review date by Corporate.

**Name of Authorized Individual (Please type or print):**
Dr. Bernard Lewin, M.D.

**Signature of Authorized Individual:** [Signature]
Lung Volume Reduction Surgery

**Policy**

I. Aetna considers lung volume reduction surgery (LVRS) medically necessary for members who meet the selection criteria outlined below. The standards for pre-operative assessment and criteria for surgery have been evolving and have varied from institution to institution. There is medical consensus that the candidate for LVRS should have severe emphysema, disabling dyspnea, and evidence of severe air trapping.

The selection criteria, which are based on the results of the National Emphysema Treatment Trial, are as follows:

A. For members with cardiac ejection fraction less than 45%, there is no history of congestive heart failure or myocardial infarction within 6 months of consideration for surgery; and

B. The member has a history and physical examination consistent with emphysema; and

C. The member has not smoked for 4 or more months; and

D. The member has all of the following on pre-operative work-up:

   1. CT scan evidence of bilateral emphysema; and

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*
2. Forced expiratory volume in 1 second (FEV1) (maximum of pre- and post-bronchodilator values) less than or equal to 45 % of predicted and, if aged 70 year or older, FEV1 15 % of predicted or more; and

3. Plasma cotinine less than or equal to 13.7 ng/ml (if not using nicotine products) or carboxyhemoglobin less than or equal to 2.5 % (if using nicotine products); and

4. Post-bronchodilator total lung capacity (TLC) greater than or equal to 100 % of the predicted value and residual volume (RV) greater than or equal to 150 % of predicted value; and

5. Resting partial pressure of carbon dioxide (PaCO2) less than or equal to 60 mm Hg on room air; and

6. Resting partial pressure of oxygen (PaO2) 45 mm Hg or greater; and

7. Six-minute walk test greater than 140 meters

E. Lung volume reduction surgery is considered experimental and investigational if the member has either of the following contraindications:

1. Post-bronchodilator FEV1 is 20 % or less than its predicted value and member has either

   a. A carbon monoxide diffusion capacity (DLCO) is 20 % or less than its predicted value. (Persons in this category have been found to be at high risk for death after LVRS, with little chance of functional benefit); or

   b. A homogenous distribution of emphysema on CT scan

2. Members with predominantly non-upper lobe emphysema and a high maximal work-load.

   a. For purposes of this policy, a high maximal workload is defined as a maximal workload (on cycle ergometry with an increment of 5 or 10 W/min after 3 mins of pedaling with the ergometer set at 0 W and the person breathing 30 % oxygen) above the sex-specific 40th percentile (25 W for women, 40 W for men).

   b. For purposes of this policy, predominantly non-upper lobe predominance of emphysema is defined to exclude disease on CT that is judged by the radiologist as affecting primarily the upper
lobes of the lung, and to include disease that is judged to be predominantly lower lobe, diffuse, or predominantly affecting the superior segments of the lower lobes.

(Note: Persons with predominantly non-upper-lobe emphysema and a high maximal work-load have been found to have higher mortality from LVRS than from medical therapy alone, and have been found to have little chance of functional improvement regardless of the treatment they receive).

F. The member should have none of the following exclusion criteria:

1. Alpha-1 antitrypsin deficiency
2. Clinically significant bronchiectasis
3. Evidence of systemic disease or neoplasia that is expected to compromise survival
4. Giant bulla (greater than 1/3 the volume of the lung in which the bulla is located)
5. History of recurrent infections with clinically significant production of sputum
6. Oxygen requirement greater than 6 L/min during resting to keep oxygen saturation greater than or equal to 90%
7. Pleural or interstitial disease which precludes surgery
8. Previous lobectomy
9. Previous LVRS (laser or excision)
10. Pulmonary hypertension, defined as mean pulmonary artery pressure of 35 mm Hg or greater on right heart catheterization or peak systolic pulmonary artery pressure of 45 mm Hg or greater. (Right heart catheterization is required to rule out pulmonary hypertension if peak systolic pulmonary artery pressure is greater than 45 mm Hg on echocardiogram)
11. Pulmonary nodule requiring surgery
12. Resting bradycardia (less than 50 beats/min), frequent multifocal premature ventricular contractions (PVCs), of complex ventricular arrhythmia or sustained supraventricular tachycardia (SVT)
13. Uncontrolled hypertension (systolic greater than 200 mm Hg or diastolic greater than 110 mm Hg)
14. Unplanned weight loss greater than 10 % within 3 months prior to consideration for surgery.

Aetna considers lung volume reduction surgery experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

II. Aetna considers bullectomy medically necessary for the treatment of dyspneic members with giant bulbous emphysema when they have a single large bulla producing significant respiratory compromise (FEV1 of less than 50 % predicted).

Aetna considers bullectomy experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.

III. Aetna considers thoracoscopic laser bullectomy experimental and investigational in the treatment of members with emphysematous lung disease because the benefit of this procedure has not been conclusively demonstrated. Furthermore, outcomes of thoracoscopic laser surgery for persons with diffuse disease need to be compared with current non-laser surgical techniques and medical therapy. Additionally, the long-term benefits of this surgery, including decreased symptoms and improved pulmonary function compared to persons without surgical intervention, need to be demonstrated.

IV. Aetna considers Food and Drug Administration (FDA)-approved endobronchial valve (e.g., the Zephyr Valve System) medically necessary for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

V. Aetna considers other bronchoscopic lung volume reduction procedures for the treatment of emphysema and all other indications experimental and investigational because of insufficient evidence of their effectiveness, including:
Biologic lung volume reduction (e.g., Aeris Therapeutics, Inc., Woburn, MA, Biologic Lung Volume Reduction (BLVR) System)

Background

Lung volume reduction surgery (LVRS) is a general term encompassing a variety of surgical procedures that are offered to alleviate the symptoms of advanced chronic obstructive pulmonary disease (COPD) due to emphysema. Currently the operations used to treat emphysema include the excision of large bullae by thoracotomy or thoracoscopy and the resection of diffusely emphysematous lung tissue.

This latter surgery, variably referred to as a lung reduction surgery, pneumectomy, and reduction pneumoplasty can be accomplished through a variety of incisions (sternotomy, clam shell, thoracotomy) or by thoracoscopy using a staple procedure or laser applications. Currently the choice of techniques depends on the surgical expertise and preference of the operator.

Based on results reported in peer review journals, abstracts and presentations at national meetings, LVRS appears efficacious for some, but not all, patients with advanced COPD due to emphysema.

Several centers have documented post-operative improvement in exertional dyspnea, measurements of pulmonary function, exercise capacity and objectively scored quality of life indices. Improvements in exercise capacity have been reported in patients undergoing a comprehensive program of pulmonary rehabilitation in preparation for surgery.

It appears that bilateral pneumectomy yields improvements in spirometry that are roughly twice as great as unilateral procedures.

In the one available randomized prospective trial that compared stapled lung reduction to laser bullectomy surgery, patients who received the latter procedure were more likely to develop a delayed pneumothorax and less likely to eliminate dependency on supplemental oxygen. Also, the mean post-operative improvement
in the forced expiratory volume in 1 second (FEV1) at 6 months was greater in those who received the stapled lung reduction technique (32.9% improvement) than the laser treatment (13.4% improvement).

Fishman et al (2003) reported on the results of the National Emphysema Treatment Trial, a randomized, multi-center clinical trial comparing LVRS with medical treatment. A total of 1,218 patients with severe emphysema were randomly assigned to undergo LVRS or to receive continued medical treatment. Lung volume reduction surgery was found to improve exercise capacity in a significant proportion of patients, but to have no significant effect on overall mortality. After 24 months, exercise capacity had improved by more than 10 W in 15% of the patients in the surgery group, as compared with 3% of patients in the medical-therapy group.

Lung volume reduction surgery was found to yield a survival advantage for patients with both predominantly upper-lobe emphysema and low base-line exercise capacity (Fishman et al, 2003). Among patients with predominantly upper-lobe emphysema and low exercise capacity, mortality was more than 50% lower in the surgery group than in the medical-therapy group.

In contrast, LVRS was associated with an increase in mortality and negligible functional gain among patients with predominantly non-upper lobe emphysema and a high base-line exercise capacity (Fishman et al, 2003). Among patients with non-upper-lobe emphysema and high exercise capacity, mortality was twice as high in the surgery group as in the medical-therapy group.

Lung volume reduction surgery was also associated with an increase in mortality among persons who were, in previous reports (National Emphysema Treatment Trial Research Group, 2001) considered to be at high-risk of death after surgery, namely patients with a low FEV1 (20% or less than predicted) and either homogenous emphysema or a very low carbon monoxide diffusing capacity (20% or less than predicted) (Fishman et al, 2003). A meta analysis (Berger et al, 2005) reported that a selected subset of patients with advanced, heterogeneous emphysema and low exercise tolerance (as indexed by the 6-min walk distance) experienced better outcomes from LVRS than from medical therapy.
Functional benefits but no improvements in survival were found in patients with predominantly upper-lobe emphysema and a high base-line exercise capacity and patients with non-upper lobe emphysema and a low base-line exercise capacity (Fishman et al, 2003).

Patients usually need pulmonary rehabilitation after LVRS to better ensure return to function.

Stoller et al (2007) noted that the role of LVRS for individuals with alpha-1 antitrypsin (AAT) deficiency is unclear. These investigators evaluated the role of LVRS in individuals with severe deficiency of AAT, and analyzed outcomes within the National Emphysema Treatment Trial. Of 1,218 randomized subjects, 16 (1.3 %) had severe AAT deficiency (serum level less than 80 mg/dL) and a consistent phenotype (when available). Characteristics of these 16 patients were 87.5 % male; median serum AAT level of 55.5 mg/dL; age of 66 years; FEV1 27 % predicted; and 50 % had upper-lobe-predominant emphysema. All 10 subjects randomized to LVRS underwent the procedure. Although the small number of subjects hampered statistical analysis, 2-year mortality was higher with surgery (20 % versus 0 %) than with medical treatment. Comparison of outcomes between the 10 AAT-deficient and the 554 AAT-replete subjects undergoing LVRS showed a greater increase in exercise capacity at 6 months in replete subjects and a trend toward lower and shorter duration FEV1 rise in deficient individuals. The authors concluded that the findings of this study extended to 49 cases the published experience of LVRS in severe AAT deficiency. Although the small number of subjects precluded firm conclusions, trends of lower magnitude and duration of FEV1 rise after surgery in AAT-deficient versus AAT-replete subjects and higher mortality in deficient individuals randomized to surgery versus medical treatment suggest caution in recommending LVRS in AAT deficiency.

Giant bullous emphysema (GBE) is a rare subset of patients with COPD in whom single or multiple large bullae encompass 30 % or more of a hemi-thorax, often displacing potentially functional lung tissue as these large airspaces increase in volume. In appropriate cases, surgical resection of these bullae can restore significant pulmonary function and improve symptoms. Computed tomography (CT) scan is essential in evaluating these patients.
According to guidelines from the Institute for Clinical Systems Improvement (ICSI, 2004), bullectomy is indicated in these patients. This is in accordance with guidelines on COPD from the Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) (NHLBI, 2005): “In carefully selected patients, this procedure is effective in reducing dyspnea and improving lung function. A thoracic computed tomography scan, arterial blood gas measurement, and comprehensive respiratory function tests are essential before making a decision regarding a patient's suitability for resection of a bulla.”

Furthermore, according to guidelines from National Institute for Clinical Excellence (NICE, 2004), patients who are breathless, and have a single large bulla on a CT scan and an FEV1 less than 50% predicted should be referred for consideration of bullectomy.

In a prospective study, Palla and colleagues (2005) evaluated patients who have undergone elective surgery due to GBE, early and late mortality following surgery, the early and late reappearance of bullae, and the early and late modifications of clinical and functional data. A total of 41 consecutive patients who underwent elective surgery for GBE were studied both before and after undergoing bullectomy for a 5-year-follow-up period. Analyses were performed on the whole population and on 2 subgroups of patients who were divided on the basis of the absence of underlying diffuse emphysema (group A; n = 23) or the presence of underlying diffuse emphysema (group B; n = 18). The early mortality rate was 7.3% (within the 1st year), and the late mortality rate was 4.9% (overall mortality rate at 5 years, 12.2%; mortality rate in group B, 27.8%). Bullae did not re-appear and residual bullae did not become enlarged in any patients at the site of the bullectomy. During the follow-up, the dyspnea score was reduced significantly soon after bullectomy and up to the fourth year of follow-up; intra-thoracic gas volume also was reduced significantly (average, 0.7 L). The same was true for the FEV1 percent predicted and the FEV1/vital capacity ratio, which kept increasing until the 2nd year; then, from the 3rd year of follow-up these values were reduced, yet remained above the pre-bullectomy values until the 5th year of follow-up. When considered separately, the patients in group B appeared to be the most impaired, clinically and functionally (e.g., FEV1 showed a similar significant increase up to the 2nd year in both groups after surgery, while a different mean annual decrease was appreciable from the second to the 5th year of follow-up: group A, 25 ml/year; group B, 83 ml/year. Furthermore, patients in group B were the only ones who contributed to the mortality rate, on the whole showing a behavior similar to that of patients who had
undergone LVRS. These investigators concluded that in patients with GBE who were enrolled in the study prospectively and were investigated yearly during a 5-year-follow-up period, bullectomy appears to have been fairly safe, and allowed clinical and functional improvement for at least 5 years. Better results may be expected in patients without underlying diffuse emphysema.

Donahue and Cassivi (2009) noted that currently alpha-1 antitrypsin deficiency (A1AD) is recognized in approximately 2% of patients who have emphysema, although this may be an under-estimation of the prevalence of this disease. Given the relatively young age at which patients who have A1AD present with emphysema, therapies aimed at slowing the progression of this disease are imperative. In addition to abstaining from smoking, the use of augmentation therapy may benefit some patients who have moderate airflow obstruction. For patients who have severe airflow obstruction, the most effective therapy is surgical. Despite a possible increased risk for infectious complications, transplantation remains a viable option for these patients who have long-term results mirroring those of patients transplanted for smoking-related COPD. Given limited donor availability, however, LVRS must be considered in these patients possibly as definitive therapy but more likely as a bridge to transplantation. Lung volume reduction surgery for patients who have A1AD remains relatively uncommon despite a general perception that it remains a surgical option. In a survey of European thoracic surgical centers, Hamacher and colleagues found that 2/3 of respondents included A1AD in their list of indications for LVRS. Although the durability of the benefits derived from LVRS in patients who have A1AD seems inferior to that of patients who have COPD, the available data show improved 6-min walk distances and decreased dyspnea persisting for 1 to 2 years after LVRS in patients who had A1AD. The authors stated that further experience is needed to determine whether or not subgroups of patients who have A1AD, such as those who have clear heterogeneous distribution, may derive more long-lasting improvement from LVRS.

Since LVRS is associated with high morbidity, mortality, and cost, several bronchoscopic methods for reducing lung volume in patients with advanced emphysema have been developed and are currently being evaluated in clinical trials as potential alternatives to LVRS. These techniques include: (i) placement of endobronchial 1-way valves designed to promote atelectasis by blocking inspiratory flow; (ii) formation of airway bypass tracts using a radiofrequency catheter designed to facilitate emptying of damaged lung regions with long
expiratory times; and (iii) instillation of biological adhesives designed to collapse and remodel hyper-inflated lung. The limited clinical data currently available suggest that all 3 techniques are reasonably safe. However, efficacy signals have been substantially smaller and less durable than those observed after LVRS. Clinical studies to optimize patient selection, refine treatment strategies, characterize procedural safety, elucidate mechanisms of action, and characterize short- and long-term effectiveness of these approaches are ongoing (Ingenito et al, 2008).

Bronchoscopic placement of small self-expanding 1-way valves into airways is a minimally invasive approach currently under investigation as an alternative to open LVRS. The valves are designed to prevent incoming airflow from reaching over-inflated regions of the lung while permitting trapped gas to escape. In addition to isolating non-functional areas of the lungs, the valves have the potential to reduce hypoxemia and hypercarbia by directing airflow to areas where gas exchange is less impaired.

The Zephyr Endobronchial Valve (EBV) (Emphasys Medical, Inc., Redwood City, CA) consists of a 1-way silicone duckbill valve attached to a self-expanding nitinol stent retainer. It is currently being evaluated in a phase III clinical trial, the Endobronchial Valve for Emphysema Palliation Trial (VENT), that compares it to optimal medical management in patients aged 40 to 75 years with heterogeneous emphysema. Patients were randomized into 2 groups: EBV procedure (n = 180) and optimal medical therapy (n = 90). Efficacy end-points include pulmonary function, exercise tolerance, and quality of life compared to baseline at various times throughout the course of 1 year. The valves are designed to be removable so the procedure has the potential to be fully reversible. The device is not yet commercially available in the United States; however, in September 2007 Emphasys Medical, Inc. submitted a pre-market application to the U.S. Food and Drug Administration (FDA) seeking approval to market the device in the U.S.

The Umbrella Implantable IntraBronchial Valve (IBV) (Spiration, Inc., Redmond, WA) consists of a polyurethane membrane over an umbrella-shaped nitinol (nickel/titanium) frame. The proximal portion is made up of 6 support stents that expand radially. The valve is designed to limit airflow distally, but the membrane and support stents allow mucociliary clearance, air and mucous to flow proximally past the valve in order to allow decompression of collateral ventilation and to reduce the hazards of mucous impaction and obstruction pneumonia. The valve
The Biologic Lung Volume Reduction (BLVR) System (Aeris Therapeutics, Inc., Woburn, MA) is an investigational procedure that uses pharmacologic agents to selectively collapse over-inflated regions of the lung. During a BLVR procedure, the physician targets diseased portions of the lung tissue with a bronchoscope and applies a washout solution to disrupt pulmonary surfactant and remove pulmonary epithelium. This causes air space to collapse on exhalation. A fibrin-based hydrogel is then applied to the treated tissue sealing it off from the rest of the lung and causing it to scar and shrink. The procedure is intended to reduce lung volume over a period of weeks as diseased lung tissue continues to collapse. It is performed in a hospital under general anesthesia and requires an overnight stay.

Aeris Therapeutics, Inc. is currently conducting a phase III study to evaluate the safety and effectiveness of the BLVR procedure. Unpublished results from two U.S. phase II studies indicated that the treatment was well-tolerated and improved pulmonary function in some emphysema patients.

The BLVR procedure may be a promising treatment for individuals with advanced upper lobe predominant emphysema; however, there is insufficient evidence of its effectiveness. Studies to determine patient selection, safety, mechanism of action, as well as short- and long-term effectiveness in patients with advanced emphysema are on-going.

In a pilot study, Snell et al (2009) reported the safety and feasibility of novel 2nd-generation bronchoscopic lung volume reduction (LVR) technology, independent of collateral ventilation. A total of 11 patients with severe heterogeneous emphysema underwent unilateral bronchoscopic application of vapor thermal energy (mean of 4.9 cal/g alveolar tissue; range of 3 to 7.5) with bronchial thermal vapor ablation (BTVA) aiming to induce a controlled inflammatory airway and parenchymal response with resultant LVR. Nine women and 2 men, with a mean age of 61
years, FEV1 of 0.77 +/- 0.17 L (32 % predicted), residual volume (RV) of 4.1 +/- 0.9 L (219 % predicted), and gas transfer of 7.8 +/- 2.2 (34 % predicted), underwent unilateral upper lobe treatments. Serious adverse events in 5 included probable bacterial pneumonia and exacerbations of airways disease in 2. Although no important FEV1 or RV changes occurred during 6 months of follow-up, gas transfer improved, 16 % to 9.0 % +/- 2.1 % (38 % predicted), the Medical Research Council Dyspnoea Score improved from 2.6 to 2.1, and the St. George Respiratory Questionnaire Total Score improved from 64.4 at baseline to 49.1. The authors concluded that these preliminary data on unilateral BTVA therapy confirm feasibility, an acceptable safety profile, and the potential for efficacy.

Eberhardt and colleagues (2009) stated that after bronchoscopic LVR, improvement in pulmonary function and exercising tolerance can be achieved in patients with severe heterogeneous lung emphysema. Feasibility and safety for 1-way valve placement in homogeneous emphysema were evaluated. A total of 10 patients entered this prospective study. In all cases, a homogeneous distribution was confirmed by computer analysis of the CT-scans. These researchers performed unilateral LVR and occluded the lobe with the lowest perfusion, measured by nuclear scintigraphy. Endpoints of the study were changes in lung function test, quality of life and 6-minute walk-test (6-MWT) at day 30 and 90 and the safety of the procedure. Pre-operative mean FEV1 was 0.93 L (range of 0.55 to 1.35 L), mean residual volume was 5.23 L (3.55 to 8.24 L) and 6-MWT was 325 m (150 to 480 m). Improvement of dyspnoe and exercising tolerance was reported in 7 cases. No major changes in lung function were evident at days 30 and 90. A trend towards improvement was observed in 6-MWT (DeltaMW + 10.4 +/- 9.8 %). One pneumothorax was noticed, in 1 case the valves were removed after 90 days because of recurrent infections. The authors concluded that the findings of this study showed that bronchoscopic LVR in patients with severe homogeneous emphysema is feasible and seems to be safe. In contrast to surgical LVR, patients may have a clinical benefit by bronchoscopic treatment. They stated that long-term follow-up and patient selection criteria have to be examined in larger trials.

In a clinical pilot study, Herth et al (2010) examined the safety and feasibility of a new endoscopic LVR approach independent of the effects of collateral ventilation (CV). Patients with severe emphysema were eligible. Inclusion and exclusion criteria were modeled after the National Emphysema Treatment Trial (NETT) study. Homogenous and heterogeneous disease was allowed. Treatment
consisted of the placement of coils into the parenchyma of the most diseased area with the intent of achieving parenchymal compression. Primary end points were safety and feasibility assessments. Secondary endpoints were efficacy outcomes. A total of 11 patients underwent 21 procedures. Procedures were performed under general anesthesia and lasted 45 +/- 15 mins and per procedure 4.9 +/- 0.6 coils were placed. All procedures were well-tolerated. The total follow-up time was 7 to 11 months and in that time 33 adverse events were reported, none of them severe. No pneumothorax occurred. Efficacy seemed better in heterogeneous rather than homogenous disease. The authors concluded that endoscopic LVR with coils is safe and feasible. Moreover, they stated that further studies of the efficacy are indicated.

Simoff et al (2013) noted that the management of obstructive lung disease, particularly emphysematous lung disease, is aggressively being pursued. The patient populations that will experience the greatest benefit with lung volume reduction are those that are the worst candidates for surgical intervention. Identifying a bronchoscopic approach that has a true impact on this patient population will be a major accomplishment in the management of patients with COPD. The authors highlighted the work currently ongoing in the area of bronchoscopic lung volume reduction. They stated that there are tools now clinically available in some locations throughout the world, but no standardized technique exists.

Song et al (2013) described the self-expanding endobronchial occluder, as utilized in bronchoscopic lung volume reduction, with a 36 month follow-up procedure. A total of 23 subjects with severe emphysema were recruited and underwent flexible bronchoscopic placement of self-expanding endobronchial occluders. Outcomes were assessed at 1 week, 1-month, 3-, 6-, 12-, 24-, and 36-month intervals. Feasibility, safety, and effectiveness were analyzed by means of pulmonary function testing, 6-min walk test, dyspnea score, BODE (body mass index, air-flow obstruction, dyspnea, and exercise capacity) index, and St George's Respiratory Questionnaire. A total of 58 self-expanding endobronchial occluders were implanted into 23 lobes previously selected. No displacement was found during the follow-up. Five subjects experienced post-operative complications of cough, and 6 subjects had lobar pneumonia, which were not located in any of the blocked segments. The FEV1 in 18 subjects was improved by greater than 15 %, compared with baselines (p < 0.001), and the mean first efficacy time and maximal efficacy time were 5.65 ± 1.51 months and 6.35 ± 3.08 months, respectively. No
significant changes were observed in FVC or the ratio of residual volume to TLC. The 6-min walk distance, dyspnea score, and St George's Respiratory Questionnaire total score were improved in 22 subjects over a 24-month period, and a minority of subjects continued to improve through to the end of the study. Mean baseline BODE index had improved during follow-up, but not at the study’s conclusion. The authors concluded that these preliminary findings demonstrated early significant improvements in pulmonary function, 6-min walk distance, dyspnea score, BODE index, and quality of life after placement of the self-expanding endobronchial occluder in bronchoscopic lung volume reduction. Its placement also proved both easy and safe. However, they noted that the initial improvements were maintained long-term for only a minority of subjects.

Stratakos et al (2013) stated that a number of bronchoscopic techniques have been developed under the term “bronchoscopic lung volume reduction”, aiming to lower the complications and the cost while facilitating the procedure of lung volume approach in patients with emphysema. These include airway bypass by creation of airway/parenchyma communications, 1-way endobronchial valves occluding the airways of the targeted lobes, endobronchial coils which mechanically contract the parenchyma, hot vapor ablation thermally destroying the targeted sites and sealant that fill the alveoli with polymer material. These methods are generally simple and safe, with a favorable complications profile, requiring less infra-structure and interventional experience than the open surgical approach. Bronchial valves have produced promising results in a very narrow phenotype of emphysema patients and have the major advantage of being reversible in their action. Parenchymal interventions at the cost of producing permanent effects and a transient inflammatory syndrome, may be effective in larger group of patients regardless of the fissure integrity and the presence of collateral ventilation. The authors noted that new, more extensive multi-center studies are underway that aim at better selection and stratification of patients in order to further evaluate the safety and effectiveness of these techniques, before wider use of this revolutionary approach for severe lung emphysema can be advocated.

Shah and Herth (2014) stated that COPD is a major cause of morbidity and mortality worldwide. Emphysema is a component of COPD characterized by hyper-inflation resulting in reduced gas exchange and interference with breathing mechanics. Endoscopic lung volume reduction using 1-way valves to induce atelectasis of the hyper-inflated lobe has been developed and studied in clinical trials over the last decade. These investigators performed searches for appropriate
studies on PubMed and Clinical Trials Databases using the search terms COPD, emphysema, lung volume reduction and endobronchial valves. The evidence from the randomized clinical trials suggested that complete lobar occlusion in the absence of collateral ventilation or where there is an intact lobar fissure are the key predictors for clinical success. Other indicators were greater heterogeneity in disease distribution between upper and lower lobes. The proportion of patients that respond to treatment improved from 20% in the unselected population to 75% with appropriate patient selection. The safety profile for endobronchial valves in this severely affected group of patients with emphysema was acceptable and the main adverse events observed were an excess of pneumothoraces. The authors concluded that selected patients have the potential of significant benefit in terms of lung function, exercise capacity and possibly even survival.

The GOLD’s clinical guideline on “Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease” (2013) states that “In a post-hoc analysis, BLVR (Bronchoscopic Lung Volume Reduction) in COPD patients with severe airflow limitation (FEV1 15% - 45% predicted), heterogeneous emphysema on computed tomography (CT) scan, and hyperinflation (total lung capacity [TLC] > 100% and residual volume [RV] > 150% predicted) has been demonstrated to result in modest improvements in lung function, exercise tolerance, and symptoms at the cost of more frequent exacerbations of COPD, pneumonia, and hemoptysis after implantation. Additional data are required to define the optimal technique and patient population”.

Furthermore, the ICSI’s clinical guideline on “Diagnosis and management of chronic obstructive pulmonary disease (COPD)” (Anderson et al, 2013) states that “Bronchoscopic LVR is being assessed in clinical trials; its role in management of COPD is yet to be defined”.

Cohen (2014) noted that COPD is a progressive, debilitating disease that in its final stages cripples the patient. The disappointing results of the National Emphysema Treatment Trial study led to a decrease in the acceptance of LVRS as a therapy. Thus, it became clear that debilitated COPD patients would need innovative alternative non-surgical procedures to potentially alleviate their symptoms. This investigator addressed the various techniques of BLVR. In recent years, a variety of non-invasive BLVR procedures were developed in the hope of improving the respiratory status of these patients. Bronchoscopic lung volume reduction aims to decrease the extent of hyper-inflation due to emphysema and result in a beneficial
effect similar to that from surgical resection. The most widely used BLVR devices are: endobronchial valves, foam sealant, metallic coils, airway bypass stents and vapor thermal ablation. In the USA, BLVR remains in the experimental phase. The treatment modalities should be individually tailored for each patient. Endobronchial valves are designed to exclude the most affected emphysematous regions from ventilation in order to induce lobar absorption atelectasis. Airway bypass stents target homogenous emphysema, whereas valves and thermal vapor ablation target heterogeneous emphysema. Biological sealants and endoscopic coil implants have been used in both homogenous and heterogeneous emphysema. The author concluded that BLVR appears to be safer than surgery and presents an attractive alternative for the treatment of COPD patients. Unfortunately, the outcome data to date are inconclusive; the procedures remain experimental and any benefits unproven. However, the data that are emerging continue to appear promising.

Bronchoscopic Lung Volume Reduction for the Treatment of Severe Emphysema

Deslee et al (2016) stated that therapeutic options for severe emphysema are limited. Lung volume reduction using nitinol coils is a bronchoscopic intervention inducing regional parenchymal volume reduction and restoring lung recoil. These researchers evaluated the safety, effectiveness, cost, and cost-effectiveness of nitinol coils in treatment of severe emphysema. They performed a multi-center 1:1 randomized superiority trial comparing coils with usual care at 10 university hospitals in France. Enrollment of patients with emphysema occurred from March to October 2013, with 12-month follow-up (last follow-up, December 2014). Patients randomized to usual care (n = 50) received rehabilitation and bronchodilators with or without inhaled corticosteroids and oxygen; those randomized to bilateral coil treatment (n = 50) received usual care plus additional therapy in which approximately 10 coils per lobe were placed in 2 bilateral lobes in 2 procedures. The primary outcome was improvement of at least 54 m in the 6-minute walk distance (6MWD) at 6 months (1-sided hypothesis test). Secondary outcomes included changes at 6 and 12 months in the 6MWD, lung function, quality of life as assessed by St George's Respiratory Questionnaire (range of 0 to 100; 0 being the best and 100 being the worst quality of life; minimal clinically important difference, greater than or equal to 4), morbidity, mortality, total cost, and cost-effectiveness. Among 100 patients, 71 men and 29 women (mean age of 62 years) were included. At 6 months, improvement of at least 54 m was observed in 18 patients (36 %) in the coil group and 9 patients (18 %) in the usual care group, for a
between-group difference of 18% (1-sided 95% confidence interval [CI] 4% to infinity [∞]; p = 0.03). Mean between-group differences at 6 and 12 months in the coil and usual care groups were +0.09 L (95% CI: 0.05 L to ∞) (p = 0.001) and +0.08 L (95% CI: 0.03 L to ∞) (p = 0.002) for forced expiratory volume in the first second, +21 m (95% CI: -4 m to ∞) (p = 0.06) and +21 m (95% CI: -5 m to ∞) (p = 0.02) for 6MWD, and -13.4 points (95% CI: -8 points to ∞) and -10.6 points (95% CI: -5.8 points to ∞) for St George's Respiratory Questionnaire (1-sided p < .001 for both). Within 12 months, 4 deaths occurred in the coil group and 3 in the usual care group. The mean total 1-year per-patient cost difference between groups was $47,908 (95% CI: $47,879 to $48,073) (p < 0.001); the incremental cost-effectiveness ratio was $782,598 per additional quality-adjusted life-year. The authors concluded that in this preliminary study of patients with severe emphysema followed-up for 6 months, bronchoscopic treatment with nitinol coils compared with usual care resulted in improved exercise capacity with high short-term costs. They stated that further investigation is needed to evaluate durability of benefit and long-term cost implications. The major drawbacks of this study were: (i) its relatively small sample size and (ii) there was no pre-selection of patients for heterogeneous emphysema. In an editorial that accompanied the aforementioned study, Sciurba et al (2016) stated that “Should the emerging data from larger pivotal trials support the meaningful clinical, albeit palliative, responses observed in preliminary trials, physicians caring for patients with COPD should not delay in providing evidence-based interventions that offer realistic hope to patients with few other choices to relieve their symptoms and improve their quality of life”.

Endobronchial Valves for Advanced Emphysema

Liu and colleagues (2015) performed a meta-analysis to evaluate the safety and effectiveness of bronchoscopic lung volume reduction with endobronchial valves (EBV) for advanced emphysema. A systematic search was performed from PubMed, Embase, CNKI, Cochrane Library database. Randomized control clinical trials on treatment of emphysema for 3 to 12 months with the EBV compared with standard medications and sham EBV were reviewed. Inclusion criteria were applied to select patients with advanced emphysema treated with EBV. The primary outcome was the percentage of the FEV1 (FEV1%). Secondary outcomes included St George's Respiratory Questionnaire (SGRQ) score, the distance of the 6MWD test, the Modified Medical Research Council (MMRC) dyspnea score, cycle ergometry workload, and the rate of the 6 major complications at 3 or 12 months. Fixed- or random-effects models were used and weighted mean differences
Lung Volume Reduction Surgery

(WMD), relative risks (RR) and 95 % CI were calculated. A total of 3 trials (565 patients) were considered in the meta-analysis; EBV patients yielded greater increases in FEV1% than standard medications (WMD = 6.71; 95 % CI: 3.31 to 10.10; p = 0.0001), EBV patients also demonstrated a significant change for SGRQ score (WMD = -3.64; 95 % CI: -5.93 to -1.34; p = 0.002), MMRC dyspnea score (WMD = -0.26; 95 % CI: -0.44 to -0.08; p = 0.004), and cycle ergometry workload (WMD = 4.18; 95 % CI: 2.14 to 6.22; p < 0.0001). A similar level was evident for 6MWD (WMD = 11.66; 95 % CI: -3.31 to 26.64; p = 0.13); EBV may increase the rate of hemoptysis (RR = 5.15; 95 % CI: 1.16 to 22.86; p = 0.03), but didn't increase the adverse events (AES) including mortality, respiratory failure, empyema, pneumonia, pneumothorax. The overall rates for complications compared EBV with standard medications and sham EBV was not significant (RR = 2.03; 95 % CI: 0.98 to 4.21; p = 0.06). The authors concluded that EBV lung volume reduction for advanced emphysema showed superior efficacy and a good safety and tolerability compared with standard medications and sham EBV. Moreover, they stated that more randomized controlled trials (RCTs) are needed to pay more attention to the long-term safety and effectiveness of bronchoscopic lung volume reduction with EBV in advanced emphysema.

In a prospective, randomized, parallel-group, double-blind, sham-controlled trial, Zoumot and associates (2015) examined if it is possible to identify patients prospectively who will reliably benefit from EBV placement. The study was performed at a single specialist center. Adult patients with heterogeneous emphysema and a target lobe with intact inter-lobar fissures were eligible if they had significant gas trapping (total lung capacity greater than 100 % predicted, residual volume greater than 150 % predicted), breathlessness [MMRC dyspnea score of greater than or equal to 3] and exercise limitation (6MWD of less than 450m). Subjects were on optimized pharmacotherapy and were non-smokers. Study participants were randomized to either unilateral lobar EBV placement aiming to achieve lobar atelectasis or bronchoscopy and “sham” valve placement. The primary end-point was improvement in FEV1 in the treatment arm compared with the control arm measured 90 days post-procedure. Secondary end-points were change in lung volumes, gas transfer, exercise capacity (both walking and endurance cycle ergometry) and health-related quality of life (QOL). In total, 50 patients were recruited, 25 to each arm; 62 % were male and mean (standard deviation) FEV1% predicted was 31.7 % (10.2 %). The primary end-point of the study was met as FEV1 increased by 24.8 % [95 % CI: 8.0 % to 41.5 %] in the treatment arm and by 3.9 % (95 % CI: 0.7 % to 7.1 %) in the control arm [between-
group difference 20.9 % (95 % CI: 4.3 % to 37.5 %); p = 0.033]. There were both statistically and clinically significant improvements in lung volumes and carbon monoxide gas transfer as well as endurance time and dynamic hyper-inflation during cycle ergometry; 2 deaths occurred in the treatment arm and 1 control patient was unable to attend for follow-up assessment because of a prolonged pneumothorax; 2 pneumothoraces occurred in the treatment arm. The authors concluded that with appropriate selection of patients through a multi-disciplinary team it is possible to produce a significant improvement in lung function through lobar occlusion with EBVs in heterogeneous emphysema. Moreover, they stated that prospective trials are needed to compare the effect of BLVR with surgical approaches in terms of magnitude and duration of benefit.

van Agteren and colleagues (2017) noted that in the recent years, a variety of BLVR procedures have emerged that may provide a therapeutic option to participants suffering from moderate-to-severe COPD. In a Cochrane review, these investigators examined the effects of BLVR on the short- and long-term health outcomes in participants with moderate-to-severe COPD and determined the effectiveness and cost-effectiveness of each individual technique. Studies were identified from the Cochrane Airways Group Specialised Register (CAGR) and by hand-searching of respiratory journals and meeting abstracts. All searches were current until December 7, 2016. They included RCTs and studies reported as full text, those published as abstract only and unpublished data, if available. Two independent review authors assessed studies for inclusion and extracted data. Where possible, data from more than 1 study were combined in a meta-analysis using RevMan 5 software. One RCT of 95 participants found that AeriSeal compared to control led to a significant median improvement in FEV1 (18.9 %, interquartile range (IQR): -0.7 % to 41.9 % versus 1.3 %, IQR: -8.2 % to 12.9 %), and higher QOL, as measured by the SGRQ (-12 units, IQR: -22 units to -5 units, versus -3 units, IQR: -5 units to 1 units), p = 0.043 and p = 0.0072, respectively. Although there was no significant difference in mortality (odds ratio (OR) 2.90, 95 % CI: 0.14 to 62.15), AEs were more common for participants treated with AeriSeal (OR 3.71, 95 % CI: 1.34 to 10.24). The quality of evidence found in this prematurely terminated study was rated low-to-moderate. Treatment with airway bypass stents compared to control did not lead to significant between-group changes in FEV1 (0.95 %, 95 % CI: -0.16 % to 2.06 %) or SGRQ scores (-2.00 units, 95 % CI: -5.58 units to 1.58 units), as found by one study comprising 315 participants. There was no significant difference in mortality (OR 0.76, 95% CI 0.21 to 2.77), nor were there significant differences in adverse events (OR 1.33, 95% CI
0.65 to 2.73) between the 2 groups. The quality of evidence was rated moderate- to-
high. Three studies comprising 461 participants showed that treatment with
endobronchial coils compared to control led to a significant between-group mean
difference in FEV1 (10.88 %, 95 % CI: 5.20 % to 16.55 %) and SGRQ (-9.14 units,
95 % CI: -11.59 units to -6.70 units). There were no significant differences in
mortality (OR 1.49, 95 % CI: 0.67 to 3.29), but AEs were significantly more common
for participants treated with coils (OR 2.14, 95 % CI: 1.41 to 3.23). The quality of
evidence ranged from low-to-high. Five studies comprising 703 participants found
that endobronchial valves versus control led to significant improvements in FEV1
(standardized mean difference (SMD) 0.48, 95 % CI: 0.32 to 0.64) and scores on
the SGRQ (-7.29 units, 95 % CI: -11.12 units to -3.45 units). There were no
significant differences in mortality between the 2 groups (OR 1.07, 95 % CI: 0.47 to
2.43), but AEs were more common in the endobronchial valve group (OR 5.85, 95
% CI: 2.16 to 15.84). Participant selection played an important role as absence of
collateral ventilation was associated with superior clinically significant
improvements in health outcomes. The quality of evidence ranged from low-to-
high. In the comparison of partial bilateral placement of intra-bronchial valves to
control, 1 trial favored control in FEV1 (-2.11 % versus 0.04 %, p = 0.001) and 1
trial found no difference between the groups (0.9 L versus 0.87 L, p = 0.065).
There were no significant differences in SGRQ scores (MD 2.64 units, 95 % CI:
-0.28 units to 5.56 units) or mortality rates (OR 4.95, 95 % CI: 0.85 to 28.94), but
AEs were more frequent (OR 3.41, 95 % CI: 1.48 to 7.84) in participants treated
with intra-bronchial valves. The lack of functional benefits may be explained by the
procedural strategy used, as another study (22 participants) compared unilateral
versus partial bilateral placement, finding significant improvements in FEV1 and
SGRQ when using the unilateral approach. The quality of evidence ranged
between moderate-to-high. One study of 69 participants found significant mean
between-group differences in FEV1 (14.70 %, 95 % CI: 7.98 % to 21.42 %) and
SGRQ (-9.70 units, 95 % CI: -15.62 units to -3.78 units), favoring vapor ablation
over control. There was no significant between-group difference in mortality (OR
2.82, 95 % CI: 0.13 to 61.06), but vapor ablation led to significantly more AEs (OR
3.86, 95 % CI: 1.00 to 14.97). The quality of evidence ranged from low-to-
moderate. The authors concluded that results for selected BLVR procedures
indicated they could provide significant and clinically meaningful short-term (up to 1
year) improvements in health outcomes, but this was at the expense of increased
AEs. They stated that the currently available evidence is insufficient to assess the
effect of BLVR procedures on mortality. These findings were limited by the lack of
long-term follow-up data, limited availability of cost-effectiveness data, significant heterogeneity in results, presence of skew and high CIs, and the open-label character of a number of the studies.

The Australian Safety and Efficacy Register of New Interventions Procedures – Surgical’s Technology Brief Update on “Endobronchial valves for patients with advanced heterogeneous emphysema” (ASERNIP, 2017) stated that “the evidence base describing the use of endobronchial valves remains immature. Data collected under the auspices of prospective evaluation clinical trials conducted in a highly selective group of patients should be encouraged. HealthPACT does not support public investment in endobronchial valves in routine clinical practice at this time”.

The National Institute for Clinical Excellence’s guidance on “Endobronchial valve insertion to reduce lung volume in emphysema” (NICE, 2017) provided the following recommendations:

- Current evidence on the safety and efficacy of endobronchial valve insertion to reduce lung volume in emphysema is adequate in quantity and quality to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- Patient selection should be done by a multi-disciplinary team experienced in managing emphysema, which should typically include a chest physician, a radiologist, a thoracic surgeon and a respiratory nurse.
- Patients selected for treatment should have had pulmonary rehabilitation.
- The procedure should only be done to occlude volumes of the lung where there is no inter-lobar collateral ventilation, by clinicians with specific training in doing the procedure.

Global Initiative for Chronic Obstructive Lung Disease’s “Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease” (GOLD, 2018) reviewed 5 studies published between 2010 and 2016 on the use of endobronchial valve for the treatment of advance emphysema. It noted that “choosing bronchoscopic lung reduction (coil placement or endobronchial valve) or surgical resection (lung volume reduction surgery, LVRS) to treat hyper-inflation in an emphysematous patient depends on a number of factors. These include: the extent and pattern of emphysema identified on high-resolution computed tomography (HRCT); the presence of interlobar collateral ventilation
measured by fissure integrity on HRCT or physiological assessment (endoscopic balloon occlusion and flow assessment); local proficiency in the performance of the procedures; and patient and provider preferences”. It stated the following:

- In selected patients with heterogeneous or homogeneous emphysema and significant hyper-inflation refractory to optimized medical care, surgical or bronchoscopic modes of lung volume reduction (e.g., endobronchial 1-way valves or lung coils) may be considered.
- In selected patients with advanced emphysema bronchoscopic intervention reduces end-expiratory lung volume and improves exercise tolerance, health status and lung function at 6 to 12 months following treatment. Endobronchial valve (Evidence: B); lung coils (Evidence: B).

On June 29, 2018, the FDA approved the Zephyr Endobronchial Valve (Zephyr Valve) that is indicated for the treatment of breathing difficulty associated with severe emphysema. The Zephyr Valve device is contraindicated for patients with active lung infections; those who are allergic to nitinol, nickel, titanium or silicone; active smokers and those who are not able to tolerate the bronchoscopic procedure. Patients who have had major lung procedures, heart disease, large bubbles of air trapped in the lung or who have not responded to other treatments should talk with their providers to determine if the Zephyr Valve device is appropriate for them.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31647</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe</td>
</tr>
<tr>
<td>31648</td>
<td>with removal of bronchial valve(s), initial lobe</td>
</tr>
<tr>
<td>31649</td>
<td>with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>31651</td>
<td>with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure[s])</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>32141</td>
<td>Thoracotomy major; with excision-plication of bullae, with or without any pleural procedure</td>
</tr>
<tr>
<td>32491</td>
<td>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</td>
</tr>
<tr>
<td>32672</td>
<td>Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31622</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)</td>
</tr>
<tr>
<td>31634</td>
<td>Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed</td>
</tr>
<tr>
<td>32124</td>
<td>Thoracotomy major; with open intrapleural pneumonolysis</td>
</tr>
<tr>
<td>32440 - 32488, 32501 - 32540</td>
<td>Excision of lung and pleura (other than for volume reduction)</td>
</tr>
<tr>
<td>32655</td>
<td>Thoracoscopy, surgical; with excision-plication of bullae, including any pleural procedure</td>
</tr>
<tr>
<td>88740</td>
<td>Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin</td>
</tr>
</tbody>
</table>

HCPCS codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0302</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services</td>
</tr>
<tr>
<td>G0303</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services</td>
</tr>
<tr>
<td>G0304</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services</td>
</tr>
<tr>
<td>G0305</td>
<td>Post discharge pulmonary surgery services after LVRS, minimum of 6 days of services</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

http://qawww.aetna.com/cpb/medical/data/100_199/0160_draft.html
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J43.0 - J43.9</td>
<td>Emphysema [except due to alpha-1-antitrypsin deficiency]</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E88.01</td>
<td>Alpha-1-antitrypsin deficiency</td>
</tr>
<tr>
<td>I27.0 - I27.2</td>
<td>Other pulmonary heart diseases</td>
</tr>
<tr>
<td>I47.1</td>
<td>Supraventricular tachycardia</td>
</tr>
<tr>
<td>R00.1</td>
<td>Bradycardia, unspecified</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


60. Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of chronic obstructive pulmonary disease (COPD). Bloomington, MN: Institute for Clinical Systems Improvement (ICSI); March 2011.


Amendment to
Aetna Clinical Policy Bulletin Number:
0160 Lung Volume Reduction Surgery

There are no amendments for Medicaid.