Lung Volume Reduction Surgery (LVRS) Certification

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
Additional Organization Eligibility Criteria	Sites that have been approved by Medicare as lung transplant facilities. Accredited facilities	
Competency	Demonstrate a strongly integrated team that exhibits expertise in pulmonary medicine, especially as it related to end-stage emphysema, pulmonary mechanics, diaphragm mechanics, pulmonary rehabilitation, thoracic surgery, critical care anesthesia, quality of life and dyspnea assessments, and pulmonary radiology assessment Providers must have clinical expertise treating emphysema patients and have a firm understanding of pulmonary medicine, pulmonary physiology and pulmonary rehabilitation. Providers must include a board certified adult pulmonary specialist of a board certified thoracic surgeon with experience performing LVRS. The surgeon must have performed a minimum of 50 bilateral LVRS surgeries by either median sternotomy of the video assisted fluoroscopic surgery with an average mortality equal to of less than 9% with an average length of hospital say of 18 days or less.	Members of the team exhibit expertise in pulmonary medicine, especially as it related to • end-stage emphysema, • functional and exercise testing, • pulmonary physiology, • pulmonary rehabilitation, • thoracic surgery, • anesthesia, and • pulmonary radiology assessment DF1.EP1 Providers must include a board certified adult pulmonary specialist AND a board certified thoracic surgeon with experience performing LVRS. DF1 EP 1 Prior to joining the program, the surgeon must have performed a minimum of 8 of each type of LVRS surgery the surgeon will perform (either as attending surgeon or surgeon) or 20 surgeries as first assist during an accredited cardiothoracic fellowship DF1 EP 1
Patient Eligibility	Acceptance Criteria - Patients must meet all criteria to be eligible for	Patients must be assessed for, and meet all criteria to be eligible for the procedure DF2EP4

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
Criteria	the procedure History and physical examination • Consistent with emphysema • BMI, ≤ 31.1 kg/m^2 (men) or ≤ 32.3 kg/m^2 (women) • Stable with ≤20 mg prednisone (or equivalent) qd Radiographic • HRCT scan evidence of bilateral emphysema Pulmonary function (prerehabilitation) • FEV_1, ≤ 45% predicted (≥ 15% predicted if age ≥70 years) • TLC, ≥100% predicted post-bronchodilator • RV, ≥150% predicted post bronchodilator Arterial blood gas level (prerehabilitation) • PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if one mile above sea level) • PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 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; LVEF cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> 5	History and physical examination ▪ Consistent with emphysema ▪ Stable with ≤20 mg prednisone (or equivalent) q day Radiographic ▪ HRCT scan evidence of bilateral emphysema Pulmonary function (pre-surgical) ▪ FEV_1, ≤ 45% predicted (≥ 15% predicted if age ≥70 years) ▪ TLC, ≥100% predicted post-bronchodilator ▪ RV, ≥150% predicted post bronchodilator Arterial blood gas level (pre-surgical) ▪ PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if one mile above sea level) ▪ PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 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; LVEF cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> 5 PVCs per minute; cardiac rhythm other than sinus; PACs on EKG at rest)

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	PVCs per minute; cardiac rhythm other than sinus; PACs on EKG at rest) Surgical assessment • Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation Exercise • Post-rehabilitation 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test Consent • Signed consents for screening, and rehabilitation. Smoking • Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products) • Nonsmoking for 4 mo prior to initial interview and throughout screening Rehabilitation/ adherence • Must complete pre-rehabilitation assessments, rehabilitation program, and all post-rehabilitation assessments Exclusion Criteria - The presence of any one criterion makes the patient ineligible for the procedure Previous surgery • Lung transplant • LVRS • Sternotomy or lobectomy Cardiovascular • Dysrhythmia that might pose a risk during	Surgical assessment ▪ Pre surgical approval for surgery by pulmonary physician, and thoracic surgeon post-rehabilitation Exercise ▪ Pre-surgical post rehabilitation 6-min walk of ≥140 m; able to complete 3 min unloaded pedaling in exercise tolerance test Smoking ▪ Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products) ▪ Nonsmoking for 4 months prior to initial interview and throughout screening Rehabilitation/ adherence • Must complete pre- rehabilitation assessments Exclusion Criteria - The presence of any one criterion makes the patient ineligible for the procedure Cardiovascular ▪ Dysrhythmia that might pose a risk during exercise or training ▪ Resting bradycardia (< 50

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	exercise or training • Resting bradycardia (< 50 beats/min); frequent multifocal PVCs; complex ventricular arrhythmia; sustained SVT • History of exercise-related syncope • MI within 6 mo and LVEF < 45% • Congestive heart failure within 6 mo and LVEF < 45% • Uncontrolled hypertension (systolic, > 200 mm; diastolic, > 110 mm) Pulmonary • History of recurrent infections with clinically significant sputum production • Pleural or interstitial disease that precludes surgery • Clinically significant bronchiectasis • Pulmonary nodule requiring surgery • Giant bulla (> 1/3 volume of lung) • Pulmonary hypertension: peak systolic PPA, ≥ 45 mm Hg (Denver criterion: ≥ 50 mm Hg) or mean PPA, ≥ 35 mm Hg (Denver criterion: ≥ 38 mm Hg). (Note: Right heart catheter is required to rule out pulmonary hypertension if peak	beats/min); frequent multifocal PVCs; complex ventricular arrhythmia; sustained SVT ▪ History of exercise-related syncope ▪ MI within 6 months and LVEF < 45% ▪ Congestive heart failure within 6 months and LVEF < 45% ▪ Uncontrolled hypertension (systolic, > 200 mm; diastolic, > 110 mm) Pulmonary ▪ History of recurrent infections with clinically significant sputum production ▪ Pleural or interstitial disease that precludes surgery ▪ Clinically significant bronchiectasis ▪ Pulmonary hypertension: peak systolic PPA, ≥ 45 mm Hg (Denver criterion: ≥ 50 mm Hg) or mean PPA, ≥ 35 mm Hg (Denver criterion: ≥ 38 mm Hg). (Note: Right heart catheter is required to rule out pulmonary hypertension if peak systolic PPA on echocardiogram is ≥ 45 mm Hg) ▪ Requirement for > 6 L O_2 to keep saturation ≥ 90% with exercise

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	systolic PPA on echocardiogram is ≥ 45 mm Hg) • Requirement for > 6 L O_2 to keep saturation ≥ 90% with exercise Radiographic • CT evidence of diffuse emphysema judged unsuitable for LVRS General • Unplanned weight loss of > 10% usual weight in 90 d prior to enrollment • Evidence of systemic disease or neoplasia expected to compromise survival during 5-yr period • 6-min walk distance ≤140 m after rehabilitation • Any disease or condition that interferes with completion of initial	General ▪ Any concurrently occurring or co morbid condition that excludes the patient from being a viable candidate. ▪ Unplanned weight loss of > 10% usual weight in 90 d prior to enrollment ▪ Evidence of systemic disease or neoplasia expected to compromise survival during 5-yr period ▪ 6-min walk distance ≤140 m after rehabilitation ▪ Any disease or condition that interferes with completion of initial assessment

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
Program Management	The organization must demonstrate the ability to perform and interpret pulmonary function studies and pulmonary and diaphragm mechanics, including a flow-volume loops, static lung volumes by body plethysmogrophy. Diffusing capacity, peak inspiratory pressures, transdiaphragmatic pressures, pressure-volume curves, elastance and resistance. The organization must demonstrate the ability to perform cardiopulmonary exercise testing including measurements of maximum workload, maximum ventilation, maximum oxygen consumption and dead space to tidal volume ratio. The organization must demonstrate the ability to assess patients for evidence of coronary heart disease and right and left heart function and pulmonary artery pressures. The organization must demonstrate the ability to perform detailed radiological assessment of the lung The organization must demonstrate the capability to support clinical need of the patient. This must include the capacity and staffing of operating rooms, recovery rooms, post-operative care facilities, pulmonary rehabilitation and other physical therapy facilities, pulmonary function laboratories, and radiological facilities. In addition, a description of the types	The program where the surgery takes place coordinates and monitors the performance of all services. PR3 EPs 1-4 The program can perform and interpret pulmonary function studies and pulmonary and diaphragm mechanics, including: PR2 EP3 ▪ flow-volume loops, ▪ static lung volumes by body plethysmogrophy. ▪ diffusing capacity The program can perform cardiopulmonary exercise testing including; PR2 EP3 • measurements of maximum workload, ▪ maximum ventilation, ▪ maximum volume at rest ▪ Maximum volume with exercise (>30% FIO_2) The program can assess patients for; PR2 EP3 ▪ evidence of coronary heart disease, ▪ right and left heart function and ▪ pulmonary artery pressures. The program can demonstrate proficiency in the measurement of Arterial Blood Gases. PR2 EP3 The program can perform detailed radiological assessment of the lung PR2 EP3 The program must be capable of supporting the clinical needs of the

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	or equipment within the pulmonary function laboratory and the pulmonary rehabilitation clinic must be provided. The organization must provide a plan for rehabilitation maintenance and education The organization must demonstrate a close working relationship with a lung or hear-lung transplantation center, thus ensuring that patients are objectively evaluated for both LVRS and lung transplant simultaneously	patient. This includes the capacity and staffing of ▪ operating rooms, ▪ recovery rooms, ▪ post-operative care facilities, ▪ pulmonary rehabilitation and other physical therapy facilities, ▪ pulmonary function laboratories, and ▪ radiological facilities. Please note – under this requirement the program will be asked to furnish the reviewer with a written description of the types or equipment within the pulmonary function laboratory and the pulmonary rehabilitation clinic as well as a detailed description of the laboratory and clinical facilities available at the program. The program must provide a plan for rehabilitation maintenance and education CT3 EP2

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
		The program has a process to obtain concurrent, objective evaluations for both LVRS and lung transplant when the patient meets lung transplant eligibility requirements DF3 EP5
Surgical Procedures	Bilateral excision of damaged lung with stapling performed via median sternotomy Video-assisted thoracoscopic surgery.	Operative procedures performed are either unilateral or bilateral excision of damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery DF2 EP5 The surgeon's privilege list indicates the specific LVRS thoracic procedures the surgeon is privileged to perform LVRS DF1 EP

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
Pulmonary Rehab program requirements	A 6 to 10 week series of at least 16, and no more than 20, preoperative sessions each lasting a minimum of two hours to. • Optimize exercise capacity • Achieve physical fitness before surgery to affect early postoperative mobilization, • Provide a baseline of optimized preoperative exercise capacity for comparison with postoperative exercise capacity Six and no more than 10 postoperative sessions each lasting a minimum of two hours, within 8 to 9 weeks of the LVRS. All participants engaged in the pulmonary rehabilitation program. Specific components of the pulmonary rehabilitation program included the following: ▪ Comprehensive evaluation of medical, psychosocial and nutritional needs ▪ Setting of goals for education and exercise training ▪ Exercise training (lower extremity, flexibility, strengthening, and upper extremity) ▪ Education about emphysema and medical treatments ▪ Psychosocial counseling ▪ Nutritional counseling	All participants are actively involved in a preoperative rehabilitation program or have completed a complementary program. DF2 EP5 The focus of the rehabilitation program is to: . DF2 EP5 • Optimize exercise capacity • Achieve physical fitness to affect early postoperative mobilization Postoperatively, participants' participle in at lease six pulmonary rehabilitation sessions within 9 weeks of the LVRS. DF2 EP5 Specific components of the pulmonary rehabilitation program include: DF2 EP5 ▪ Comprehensive evaluation of medical, psychosocial and nutritional needs ▪ Setting of goals for education and exercise training ▪ Exercise training (lower extremity, flexibility, strengthening, and upper extremity) ▪ Education about emphysema and medical treatments ▪ Psychosocial counseling ▪ Nutritional counseling
Performance Improvement/ Measurement	The organization provides pre-operative, post –operative and follow-up data including LOS, surgical and medical complication rates and early (≤ 30 days) and late mortality.	
Other	Consistent with the care plan	The plan of care is consistent with

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
requirements	developed by the treating physician Arranged, monitored and performed under the coordination of the organization where the surgery takes place.	the care plan developed by the treating physician DF3 EP7
Informed consent process	Written document Understandable at all educational levels - appropriate for the potential recipient's level of education but certainly written for readers with no higher than an 8th or 9th grade level of education. If the potential recipient does not speak English, there should be an independent interpreter to facilitate understanding in the patient's language. Where appropriate, translations of such a document and accompanying materials should be made available. The following elements be incorporated in the informed consent document given to the potential LVRS recipient, with specific descriptions that would ensure the patient's awareness of: 1. The evaluation process 2. The surgical procedure 3. Alternative treatments 4. Potential medical risks such as infection and bleeding with provision of national and center-specific rates 5. National and center-	

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	specific short-term and long-term mortality 6. National and center-specific outcomes other than mortality 7. National and center-specific hospital lengths of stay 8. Potential risk factors that could affect the immediate or future success of the surgery or the health of the patient, such as the patient's history 9. His or her right to refuse the surgery Each organization will train and assign to each potential LVRS patient an independent advocate who will assist the operating team and organization-supporting staff in ensuring that full disclosure occurs. These informed consent requirements will be made a part of the organization accreditation criteria.	
Outcomes of interest extracted from Medicare Payment Decision Document (consistent with other literature)	Survival rates • Operative mortality • Early mortality (defined as hospital deaths or deaths occurring within 30 days of surgery) • Late mortality (deaths occurring in the home or more than 30 days after surgery) Complication rates • Prolonged air leak • Pneumonia • Cardiovascular events • Reoperations	The program provides data including; PM2 EP1 ▪ Post operative length of stay (acute care and rehab facility LOS) ▪ surgical and medical complication rates and ▪ Mortality $\underline{< 90}$ days.

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	Exercise capacity • Maximal, incremental, symptom-limited cycle ergometry (e.g., using a cycle ergometer with five or 10 watt/minute ramp on 30% oxygen, after three minutes of unloaded pedaling) and the 6-min walk test. (NETT) • Walk distance improvement from baseline after surgery. • Maximum exercise capacity two years after randomization. (NETT) Patient-reported quality of life (Resp symptoms and pulmonary also reported under QOL) • Medical Outcomes Study Short Form 36-item (MOS SF-36) • Utility-weighted Quality of Well-Being Scale (QWB). • St. George Respiratory Questionnaire (SGRQ) Respiratory symptoms • St. George's Respiratory Questionnaire (SGRQ) • University of California at San Diego Shortness of Breath Questionnaire (SOBQ). • Borg scale • Modified Medical Research Council (MMRC) dyspnea scale • Mahler baseline dyspnea index (BDI) • Transitional dyspnea index (TDI) Pulmonary function.	

Major Element	National Emphysema Treatment Trial (NETT) Study Requirements	Joint Commission Expectations
	• Forced expiratory volume in one second (FEV1), • Forced vital capacity, • Total lung capacity • Residual volume • Carbon monoxide diffusing capacity (percent predicted). • Arterial blood gas measurements including PCO2 (mm Hg) and PO2 (mm Hg). Cognitive abilities. • Trail Making Test (attention and psychomotor functioning). Cost effectiveness. • Incremental quality-adjusted life years (QALYs) BMI = body mass index HRCT = high-resolution computed tomography; LVEF = left ventricular ejection fraction; PAC = premature atrial contraction; PVC = premature ventricular contraction; RV = residual volume; TLC = total lung capacity.	