Left Ventricular Assist Device (LVAD) Insertion

2017.1 Procedures Criteria

PATIENT:	Name	DOB	ID#	GROUP#
	Facility		Service Date	
PROVIDER:	Name		Fax#	Phone#
	Signature		Date	NPI/ID#

ICD-10:
CPT®:

Subset: Left Ventricular Assist Device (LVAD) Insertion[1, 2, 3, 4, 5]
Requested Service: Left Ventricular Assist Device (LVAD) Insertion
Age:[6] Age ≥ 18

INSTRUCTIONS: Answer the following questions[7, 8, 9]

☐ **New York Heart Association Class IIIb or IV heart failure (HF)**

1. Choose one:[10]

☐ A) Patient listed for cardiac transplant[11]
☐ B) Patient ineligible for cardiac transplant[12, 13]
☐ C) Other clinical information (add comment)

- If option A selected, then go to question 2
- If option B selected, then go to question 4
- No other options lead to the requested service

2. Choose all that apply:

☐ A) Continued symptoms despite optimal medical treatment[14, 15]
☐ B) No active infection or infection treated[16]
☐ C) No irreversible coagulopathy[17]
☐ D) Life expectancy ≥ 2 years[18]
☐ E) No aortic regurgitation (AR) ≥ 2+ or aortic regurgitation (AR) repaired[19]
☐ F) No history of mechanical aortic valve or mechanical valve replaced[19]
☐ G) Other clinical information (add comment)

- If the number of options selected is 6 and option G not selected, then go to question 3
- No other options lead to the requested service

3. Choose all that apply:

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3. Choose all that apply: ***(Continued...)***

- ☐ A) Patient or caregiver demonstrates functional ability to maintain and operate left ventricular assist device (LVAD)[20]
- ☐ B) Patient has adequate social or family support[21]
- ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here ***(Inpatient)***
- No other options lead to the requested service

4. Choose all that apply:

- ☐ A) Continued symptoms despite optimal medical treatment[14]
- ☐ B) IV inotropes ≥ 2 weeks[15]
- ☐ C) Temporary mechanical circulatory support ≥ 1 week[22]
- ☐ D) Other clinical information (add comment)

- If 1 or more options A, B or C selected and option D not selected, then go to question 5
- No other options lead to the requested service

5. Choose all that apply:

- ☐ A) Ejection fraction (EF) ≤ 30% by testing[23]
- ☐ B) Peak VO_2 ≤ 14 ml/kg/min[24, 25]
- ☐ C) No active infection or infection treated[16]
- ☐ D) No irreversible coagulopathy[17]
- ☐ E) No irreversible renal disease[26]
- ☐ F) Life expectancy ≥ 2 years[18]
- ☐ G) No aortic regurgitation (AR) ≥ 2+ or aortic regurgitation (AR) repaired[19]
- ☐ H) No history of mechanical aortic valve or mechanical valve replaced[19]
- ☐ I) Other clinical information (add comment)

- If the number of options selected is 8 and option I not selected, then go to question 6
- No other options lead to the requested service

6. Choose all that apply:

- ☐ A) Patient or caregiver demonstrates functional ability to maintain and operate left ventricular assist device (LVAD)[20]
- ☐ B) Patient has adequate social or family support[21]
- ☐ C) Other clinical information (add comment)

- If the number of options selected is 2 and option C not selected, then the rule is satisfied; you may stop here ***(Inpatient)***
- No other options lead to the requested service

Notes

(1)
I/O Setting: Inpatient

(2)
These criteria do not cover the insertion of a percutaneous left ventricular assist device (LVAD) used to protect the heart during invasive procedures or a temporary LVAD for short-term mechanical circulatory support while treatment decisions are made.

(3)
Def: A left ventricular assist device (LVAD) consists of either an internal or external mechanical pump that is inserted surgically below the diaphragm. Cannulas, attached to the pump and inserted into the left ventricle and aorta, bypass the failing ventricle and help improve cardiac output and end-organ blood flow.

(4)
Because poor nutritional status predisposes patients to infection, impaired healing, and higher mortality, heart failure patients should have their nutritional status optimized prior to implantation of a left ventricular assist device (LVAD) (Peura et al., Circulation 2012, 126: 2648-67). Although not a contraindication to LVAD insertion, obesity increases surgical risk and complications (e.g., driveline infection) (Feldman et al., J Heart Lung Transplant 2013, 32: 157-87).

(5)
InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare &Medicaid Services (CMS) National Coverage Determinations, the National Institute of Health and Care Excellence (NICE), and the National Guideline Clearinghouse. Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

(6)
These criteria address adult diagnoses or indications. Although there may be diagnoses or indications that are medically appropriate in individuals < 18, these are not currently addressed.

(7)
Despite the use of conventional therapies, patients with refractory end-stage heart failure characteristically experience rapid recurrence of symptoms at rest or with moderate exertion, are unable to perform ADLs, and have repeated or prolonged hospital stays for intensive management (Yancy et al., Circulation 2013, 128(16):e240-319; National Clinical Guideline Centre, Chronic heart failure: the management of chronic heart failure in adults in primary and secondary care. 2010). Without transplantation, these patients generally survive less than one year.

(8)
New York Heart Association Class III or IV heart failure:
III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
IIIb: Marked limitation of physical activity. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain. Dyspnea present at rest.
IV: Inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

(9)
Although left ventricular assist device (LVAD) insertion had initially been shown to be most beneficial in patients with New York Heart Association (NYHA) Class IV heart failure, the recent development of more durable, safer LVADs has allowed for patients to receive the device prior to progression to Stage IV HF (Peura et al., Circulation 2012, 126: 2648-67; Slaughter et al., N Engl J Med 2009, 361: 2241-51).

(10)
Cardiac transplant outcomes have improved with advancements in immunosuppressive medications. Survival rates of 88% and 75% at one and five years, respectively, have been reported (U.S. Department of Health and Human Services. Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 2003-2013. 2013).

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(11)
Although cardiac transplant remains the treatment of choice for patients with end-stage heart failure, approximately 10% of patients who meet criteria for transplant die waiting for an organ. Because there may be a significant interval between when a patient is first deemed a transplant candidate (i.e., put on the transplant list) and when an organ is actually received, a left ventricular assist device (LVAD) may provide a bridge for patients who otherwise would not survive until an organ is available due to hemodynamic instability (e.g., low cardiac output). In 2013, 27% of cardiac transplant candidates were listed for transplant with a ventricular assist device in place. This number tripled from years past (U.S. Department of Health and Human Services. Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 2003-2013. 2013). Although there have been no randomized comparisons of LVAD therapy with optimal medical therapy in patients awaiting cardiac transplantation, the results of nonrandomized trials and case studies have shown that LVAD insertion may allow for increased exercise capacity, improved end-organ perfusion, reversal of unresponsive pulmonary hypertension, and improved quality of life (Peura et al., Circulation 2012, 126: 2648-67).

(12)
Left ventricular assist device (LVAD) insertion is an increasingly utilized treatment strategy for patients who are not candidates for transplantation but require mechanical support for the treatment of advanced heart failure. This accounts for approximately 40% of all LVAD placement (Kirklin et al., J Heart Lung Transplant 2014, 33: 555-64). Also known as destination therapy, the use of an LVAD for this indication is based on the results of the landmark Randomized Evaluation of Mechanical Assistance in the Treatment of Congestive Heart Failure (REMATCH) study which showed that New York Heart Association (NYHA) class IV heart failure patients ineligible for heart transplantation who were supported with an LVAD had an estimated one-year survival of 52% compared with 25% in patients who received maximal medical therapy alone (Rose et al., N Engl J Med 2001, 345: 1435-43). The more recent Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients (ROADMAP) ongoing trial showed preliminary results of an 80% one-year survival in patients treated with an LVAD compared with 64% in patients treated medically (Estep et al., J Am Coll Cardiol 2015, 66: 1747-61).

(13)
Patients who may not initially be candidates for transplantation and receive a left ventricular assist device (LVAD) may become transplant eligible if the LVAD provides significant improvement in comorbidities that previously precluded transplantation. For example, patients may see recovery in renal function, a decrease in pulmonary hypertension, or weight loss with placement of an LVAD. Between 2006 and 2011 there were 2,800 patients who received an LVAD and were not candidates for transplant and of these, 15% went on to become transplant candidates (Teuteberg et al., JACC Heart Fail 2013, 1: 369-78).

(14)
Medical treatment in patients with heart failure (HF) should include beta blockers and angiotensin converting enzyme (ACE) inhibitors. Beta blockers (e.g., carvedilol) and ACE inhibitors (e.g., lisinopril) have been shown to reduce mortality and morbidity. Patients who are intolerant of ACE inhibitors may benefit from angiotensin receptor blockers (ARBs) (e.g., cozaar). Diuretics (e.g., furosemide) are recommended in patients with evidence of fluid retention. Aldosterone receptor antagonists (e.g., spironolactone) have been shown to reduce mortality and HF hospitalizations in patients with New York Heart Association Class II to IV HF and an ejection fraction of 35% or less; however, careful monitoring for hyperkalemia and renal insufficiency is required. Patients with chronic heart failure, who remain symptomatic, may benefit from replacement of their ACE inhibitor or ARB with an angiotensin receptor neprilysin inhibitor. Alternately, another newer option for patients is Ivabradine. Its ability to provide heart rate reduction has shown a reduction in hospitalizations (Ponikowski et al., Eur J Heart Fail 2016, 18: 891-975; Yancy et al., J Am Coll Cardiol 2016, 68: 1476-88; Yancy et al., Circulation 2013, 128(16):e240-319).

(15)
Inotropes (e.g., dopamine, dobutamine, milrinone) are effective treatments for heart failure when symptomatic hypotension or low cardiac output is present. Temporary inotropic support can be effective in treating patients who are unable to tolerate or do not respond to vasodilators and diuretics. Patients treated with inotropes are at a higher risk for adverse outcomes and require close hemodynamic monitoring (Yancy et al., Circulation 2013, 128(16):e240-319).

(16)
Left ventricular assist device insertion should not be considered in patients with active systemic infection, as it is one of the leading causes of morbidity, mortality, and hospital re-admission in this patient population (Kirklin et al., J Heart Lung Transplant 2014, 33: 555-64; Slaughter et al., J Heart Lung Transplant 2010, 29: S1-39).

(17)
Bleeding is a common complication with left ventricular assist devices (LVAD) and since systemic anticoagulation and antiplatelet therapy are often both required with LVAD placement, patients with coagulopathy may not be candidates (Peura et al., Circulation 2012, 126: 2648-67).

(18)
Patients with coexisting illnesses (e.g., metastatic or advanced cancer, severe neuromuscular disorders) that may limit their life expectancy to less than two years should not undergo left ventricular assist device insertion (Feldman et al., J Heart Lung Transplant

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2013, 32: 157-87; Lund et al., Eur J Heart Fail 2010, 12: 434-43).

(19)

Aortic regurgitation (AR) in patients who undergo left ventricular assist device (LVAD) insertion can result in ventricular distention, hemodynamically compromising volume overload of the LVAD, and inadequate forward flow. Because the effectiveness of the device depends on a competent aortic valve, patients with moderate to severe AR should have this surgically corrected prior to consideration of LVAD. A pre-existing mechanical aortic valve should be replaced with a bioprosthetic valve or sewn shut prior to LVAD placement, as patients with a mechanical valve are at an increased risk of thromboembolism with LVAD (Feldman et al., J Heart Lung Transplant 2013, 32: 157-87; Peura et al., Circulation 2012, 126: 2648-67).

(20)

The patient and caregiver must be assessed for their ability and willingness to participate in the care and maintenance of the device including: daily monitoring of the device; response to alarms; dressing changes; inspecting for infection; assessing the status of the batteries; and preparedness for emergencies that may occur with the device. Patients with a history of stroke, neuropathy, musculoskeletal disease, or impaired cognitive function, as well as patients with other comorbidities that may preclude their ability to operate the device and respond to alarms (e.g., blindness, deafness, obesity), should be evaluated carefully prior to left ventricular assist device insertion (Feldman et al., J Heart Lung Transplant 2013, 32: 157-87; Wilson et al., J Am Coll Cardiol 2009, 54: 1647-59).

(21)

Patients and their families face a unique set of stressors when a left ventricular assist device (LVAD) is required, including loss of independence, fear of being able to adequately manage the device, caregiver burden, and fear of dying. Patients and their caregivers should be screened for psychological and emotional readiness and adequate support prior to LVAD insertion (Bruce et al., J Card Fail 2014, 20: 996-1003; Feldman et al., J Heart Lung Transplant 2013, 32: 157-87).

(22)

Temporary mechanical circulatory support (e.g., intraaortic balloon pump, extracorporeal membrane oxygenation, percutaneous ventricular assist devices) may be used to support a patient in advanced heart failure when medical management fails to improve symptoms or hemodynamics (Peura et al., Circulation 2012, 126: 2648-67).

(23)

Testing includes imaging by transthoracic echocardiogram, transesophageal echocardiogram, left ventriculogram, or radionuclide ventriculogram.

(24)

Def: Peak VO_2 is defined as the amount of oxygen consumed in the last 20 to 30 seconds of exercise at maximum exertion.

(25)

Peak VO_2, measured during cardiopulmonary exercise testing, is used as a prognostic indicator in patients with heart failure. Studies have shown that the mortality rate in patients with a peak VO_2 less than 14 mL/kg/min is nearly double that of patients whose peak VO_2 exceeds this value (Milani et al., Mayo Clin Proc 2006, 81: 1603-11). Cardiac transplantation or left ventricular assist device placement should be considered in these patients (Lindenfeld et al., J Card Fail 2010, 16: e1-194).

(26)

Left ventricular assist device placement is not recommended in patients with advanced kidney disease in whom renal function is unlikely to recover despite improved hemodynamics and who are, therefore, at high risk for progression to dialysis (Peura et al., Circulation 2012, 126: 2648-67).

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ICD-10-CM (circle all that apply): I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.9, Other_____

ICD-10-PCS (circle all that apply): 02HA0QZ, 02HA0RS, 02HA0RZ, 02HA3QZ, 02HA3RS, 02HA3RZ, 02HA4QZ, 02HA4RS, 02HA4RZ, 5A02216, Other_____

CPT® (circle all that apply): 33975, 33976, 33979, Other_____