

Left Ventricular Assist Device SRG-021

Iowa Medicaid Program:	Prior Authorization	Effective Date:	7/1/2021
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Reviewed By:	Medicaid Medical Director	Next Rev Date:	7/18/2025
Approved By:	Medicaid Clinical Advisory Committee	Approved Date:	7/16/2021

Descriptive Narrative

Heart failure (HF) is a condition in which the heart cannot pump blood adequately to meet the body's needs at rest or with exertion. About 6.5 million people in the United States have been diagnosed with HF. This condition is associated with significant mortality, morbidity, and healthcare expenditures, particularly among those 65 years of age or older. In addition to age, which is an independent risk factor for heart failure, older adults often have other risk factors such as hypertension, diabetes, coronary heart disease, tobacco use, and may be overweight/obesity; patients may have been exposed to these risk factors for many years.

When the heart fails to pump blood adequately, the body retains excess fluid and tissues do not get enough oxygen. This results in symptoms which may include shortness of breath, swelling of the legs, and fatigue and leads to substantial morbidity and mortality. HF is the leading cause of hospitalization among older adults and Medicare beneficiaries with HF have the highest readmission rate of any chronic condition. HF contributes to at least 287,000 deaths annually in the United States.

While there are objective measures of the severity of heart failure such as ejection fraction and cardiopulmonary exercise testing, care is most often driven by symptom-based classifications including the New York Heart Association (NYHA) Functional Classification, INTERMACS profiles, and the American Heart Association and American College of Cardiology (AHA/ACC) Stages of Heart Failure (see tables on following pages).

Left ventricular assist devices (LVAD) are mechanical blood pumps which are surgically attached to one or both intact ventricles of a damaged or weakened native heart to assist in pumping blood. The heart remains intact with VADs, allowing the possibility for the native heart to recover and permit the patient to undergo subsequent removal of the device. Patients who may be candidates for LVAD implantation undergo extensive clinical testing to ensure an adequate severity of heart failure as well as acceptable severity of comorbidities. This evaluation attempts to balance the benefits that may be achieved by LVAD implantation with the significant risks of the surgery and prolonged device support. Initially LVADs were used for patients who needed short-term support due to acute heart failure, caused by temporary conditions such as infection or open heart surgery.

With the development of smaller implantable pumps, patients can be ambulatory, discharged from the hospital, and supported on the device for longer periods. These durable LVADs were first introduced in patients on the heart transplant waitlist as a “bridge to transplant (BTT)” since the duration of support was intended to be finite. With heart transplants in limited supply and additional clinical experience gained, devices were subsequently implanted as “destination therapy (DT)” in patients who were ineligible for heart transplant and required permanent support. Heart failure patients that are candidates for LVAD therapy who are not classified as either BTT or DT at the time of LVAD implantation are referred to as “bridge to decision” or “bridge to candidacy (BTC).”

There is now evidence that LVAD unloading can promote recovery of myocardial function. This recovery can be sufficient to allow device removal without cardiac transplantation and leave the patient with an improved functional capacity and quality of life. The strategy of device implantation to promote recovery of myocardial function is known as “bridge to recovery (BTR).” Usually, however, the device is not implanted specifically as BTR but as DT or BTT and then, if sufficient myocardial recovery has taken place, explantation of the pump is considered.

Some patients transition between the categories of BTT, BTC, and DT over time with the development or resolution of comorbid conditions. In addition, this categorization can be inconsistent due to differences in transplant approval and listing processes at individual transplant hospitals.

NYHA and other classifications of cardiovascular disability

Class	NYHA functional classification ^[1]	Canadian Cardiovascular Society functional classification ^[2]	Specific activity scale ^[3]
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous or rapid prolonged exertion at work or recreation.	Patients can perform to completion any activity requiring ≥ 7 metabolic equivalents (ie, can carry 24 lb up 8 steps; do outdoor work [shovel snow, spade soil]; do recreational activities [skiing, basketball, squash, handball, jog/walk 5 mph]).
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress, or only during the few hours after awakening. Walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and in normal conditions.	Patients can perform to completion any activity requiring ≥ 5 metabolic equivalents (eg, have sexual intercourse without stopping, garden, rake, weed, roller skate, dance foxtrot, walk at 4 mph on level ground) but cannot and do not perform to completion activities requiring ≥ 7 metabolic equivalents.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less-than-ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking 1 to 2 blocks on the level and climbing 1 flight in normal conditions.	Patients can perform to completion any activity requiring ≥ 2 metabolic equivalents (eg, shower without stopping, strip and make bed, clean windows, walk 2.5 mph, bowl, play golf, dress without stopping) but cannot and do not perform to completion any activities requiring > 5 metabolic equivalents.
IV	Patients with cardiac disease resulting in 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.	Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.	Patients cannot or do not perform to completion activities requiring > 2 metabolic equivalents. Cannot carry out activities listed above (specific activity scale III).

NYHA: New York Heart Association. References:

¹The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed, Little, Brown & Co, Boston 1994. p.253.

²Campeau L. Grading of angina pectoris. Circulation 1976; 54:522.

³Goldman L, Hashimoto B, Cook EF, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: Advantages of a new specific activity scale. Circulation 1981; 64:1227.

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INTERMACS

INTERMACS profiles were developed to further classify patients with advanced NYHA class III and class IV heart failure into one of seven profiles:

- Profile 1 - Critical cardiogenic shock: Patient with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels.
- Profile 2 – Progressive decline: Patient with declining function despite intravenous inotropic support, may manifest with worsening renal function, nutritional depletion, or inability to restore volume balance. Also describes declining status in patients unable to tolerate inotropic therapy.
- Profile 3 - Stable but inotrope dependent: Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support (or a temporary circulatory support device or both), but demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction.
- Profile 4 - Resting symptoms: Patient who can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during activities of daily living. Doses of diuretics generally fluctuate at very high levels.
- Profile 5 - Exertion intolerant: Patient who is comfortable at rest and with activities of daily living but is unable to engage in any other activity, living predominantly within the house.
- Profile 6 - Exertion limited: Patient without evidence of fluid overload who is comfortable at rest, and with activities of daily living and minor activities outside the home but fatigues after the first few minutes of any meaningful activity.
- Profile 7 - Advanced NYHA class III: Patient who is clinically stable with a reasonable level of comfortable activity, usually able to walk more than a block. Has a history of previous decompensation but any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a patient profile 6 or lower.

AHA/ACC Stages

The American Heart Association/American College of Cardiology Stages emphasize the development and progression of heart failure ranging from Stage A (risk factors but no current cardiac abnormality) to Stage D (refractory heart failure, may be eligible for advanced treatments such as continuous inotropes, heart transplant, VAD placement, or end-of-life care).

Criteria

Prior authorization is required.

Bridge to Transplantation

Implantation of an LVAD is considered medically necessary when **ALL** the following are met:

1. The device is FDA approved and is being used in accordance with FDA approval; **AND**
2. Presence of severe end stage heart failure; **AND**
3. Not expected to survive until a donor heart can be obtained; **AND**
4. Currently listed as a heart transplant candidate; **OR** undergoing evaluation to determine eligibility for a heart transplant.

Bridge to Recovery

Implantation of an LVAD is considered medically necessary when **ALL** the following are met:

1. The device is FDA approved and is being used in accordance with FDA approval; **AND**
2. Member is post cardiectomy; **AND**
3. Member is unable to be weaned off cardiopulmonary bypass.

Implantation of a percutaneous LVAD is considered medically necessary when **ALL** the following are met:

1. The device is FDA approved and is being used in accordance with FDA approval; **AND**
2. Member requires short term support management for conditions such as post cardiectomy shock or bridge to recovery.

Destination Therapy

Implantation of an LVAD is considered medically necessary when **ALL** the following are met:

1. The device is FDA approved and is being used in accordance with FDA approval; **AND**
2. Member has undergone evaluation and determined not to be eligible for heart transplant; **AND**
3. Documentation of Class III or IV NYHA end-stage left ventricular heart failure; **AND**
4. Member has a life expectancy of less than 2 years; **AND**
5. **ONE** of the following have been met:
 - a. Member has received optimal medical management for at least 45 of the past 60 days; **OR**
 - b. Member's survival is in jeopardy.

Contraindications to LVAD Implantation

1. Life expectancy in the absence of heart disease is 2 years or less.
2. Malignancy within past 5 years that is expected to significantly limit survival.
3. Irreversible renal or hepatic dysfunction, severe obstructive pulmonary disease, or other systemic disease with multi-organ involvement.
4. A pattern of demonstrated noncompliance or lack of sufficient caregiver support which would place an LVAD at serious risk of failure.
5. Active substance or alcohol abuse.
6. Unmanaged psychiatric disorder.
7. Persistent, recurrent, or unsuccessfully treated major or systemic infections.

Coding

The following list(s) of codes are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

CPT	Description
33979	Insertion of ventricular assist device; implantable intracorporeal, single ventricle.
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle.
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump.
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass.
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass.
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only.
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transeptal puncture.
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only.
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion.

HCPCS	Description
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type.
Q0479	Power module for use with electric or electric/pneumatic ventricular assist device, replacement only.
Q0480	Driver for use with pneumatic ventricular assist device, replacement only.
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only.
Q0482	Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only.
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only.
Q0484	Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only.
Q0485	Monitor control cable for use with electric ventricular assist device, replacement only.
Q0486	Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only.

HCPCS	Description
Q0487	Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only.
Q0488	Power pack base for use with electric ventricular assist device, replacement only.
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only.
Q0508	Miscellaneous supply or accessory for use with an implanted ventricular assist device.
Q0509	Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A.

ICD-10	Description
02HA0QZ	Insertion of implantable heart assist system into heart [by approach;].
02HA3QZ	Insertion of implantable heart assist system into heart [by approach;].
02HA4QZ	Insertion of implantable heart assist system into heart [by approach;].
02WA0QZ	Revision of implantable heart assist system in heart [by approach;].
02WA3QZ	Revision of implantable heart assist system in heart [by approach;].
02WA4QZ	Revision of implantable heart assist system in heart [by approach;].
5A02116	Assistance with cardiac output using other pump, intermittent.
5A02216	Assistance with cardiac output using other pump, continuous.
I50.1	Left ventricular failure, unspecified.
I50.20	Unspecified systolic (congestive) heart failure.
I50.82	Biventricular heart failure.
I50.84	End stage heart failure.
I50.9	Heart failure, unspecified.
I97.0	Postcardiotomy syndrome.
Z95.811	Presence of heart assist device.
Z76.82	Awaiting organ transplant status.

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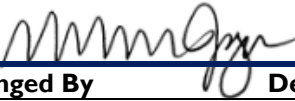

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Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History			
Change Date	Changed By	Description of Change	Version
Signature			
Change Date	Changed By	Description of Change	Version
Signature			
Change Date	Changed By	Description of Change	Version
7/19/2024	CAC	Annual review	4
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Change Date	Changed By	Description of Change	Version
7/21/2023	CAC	Annual review	3
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Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
7/15/2022	CAC	Criteria and codes added under bridge to recovery. References updated. Formatting changes.	2
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
7/16/2021	CAC	Criteria implementation.	1
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