MASSACHUSETTS

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Medical Policy

Total Artificial Hearts and Implantable Ventricular Assist Devices

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Policy Number: 280

BCBSA Reference Number: 7.03.11
NCD/LCD: National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9)

Related Policies

Heart/Lung Transplant, #269
Heart Transplant, #197
Extracorporeal Membrane Oxygenation, #726

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

BRIDGE TO TRANSPLANTATION

Implantable ventricular assist devices with FDA approval or clearance may be considered **MEDICALLY NECESSARY** as a bridge to heart transplantation for patients who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Implantable ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions (HDEs), may be considered **MEDICALLY NECESSARY** as a bridge to heart transplantation in children 16 years old or younger who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Total artificial hearts with FDA-approved devices may be considered **MEDICALLY NECESSARY** as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

DESTINATION THERAPY

Implantable ventricular assist devices with FDA approval or clearance may be considered **MEDICALLY NECESSARY** as destination therapy with end stage heart failure patients who are ineligible for human heart transplant and who meet the following “REMATCH Study” criteria:

- NYHA class IV heart failure for >60 days, OR patients in NYHA class III/IV for 28 days, received ≥14 days' support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:

- Age >65 years; OR
- Insulin-dependent diabetes mellitus with end-organ damage; OR
- Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days); OR
- Presence of other clinically significant condition.

POSTCARDIOTOMY SETTING/BRIDGE TO RECOVERY
Implantable ventricular assist devices with U.S. Food and Drug Administration (FDA) approval or clearance may be considered **MEDICALLY NECESSARY** in the postcardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

OTHER INDICATIONS
Other applications of implantable ventricular devices or total artificial hearts are considered **INVESTIGATIONAL**, including, but not limited to, the use of total artificial hearts as destination therapy.

The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered **INVESTIGATIONAL**.

Percutaneous ventricular assist devices are considered **INVESTIGATIONAL** for all indications.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9)

For a list of Medicare-approved facilities:
http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	N/A
Commercial PPO and Indemnity	N/A
Medicare HMO Blue℠	N/A
Medicare PPO Blue℠	N/A

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Removal of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricular
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; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
93750	Interrogation of ventricular assist device, in person, with physician analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow volume status, septum status, recovery), with programming, if performed, and report

HCPCS Codes

HCPCS codes:	Code Description
L8698	Miscellaneous component, supply or accessory for use with total artificial heart system
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only
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
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
Q0490	Emergency power source for use with electric ventricular assist device, replacement only
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only
Q0492	Emergency power supply cable for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0493	Emergency power supply cable for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0494	Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0496	Battery for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0499	Belt/vest for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0500	Filters for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0502	Mobility cart for pneumatic ventricular assist device, replacement only
Q0503	Battery for pneumatic ventricular assist device, replacement only, each
Q0504	Power adapter for pneumatic ventricular assist device, replacement only, vehicle type
Q0506	Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	**Code Description**
02RK0JZ	Replacement of Right Ventricle with Synthetic Substitute, Open Approach
02HA0QZ	Insertion of Implantable Heart Assist System into Heart, Open Approach
02HA0RS	Insertion of Biventricular External Heart Assist System into Heart, Open Approach
02HA0RZ	Insertion of External Heart Assist System into Heart, Open Approach
02HA3QZ	Insertion of Implantable Heart Assist System into Heart, Percutaneous Approach
02HA3RS	Insertion of Biventricular External Heart Assist System into Heart, Percutaneous Approach
02HA3RZ	Insertion of External Heart Assist System into Heart, Percutaneous Approach

02HA4QZ	Insertion of Implantable Heart Assist System into Heart, Percutaneous Endoscopic Approach
02HA4RS	Insertion of Biventricular External Heart Assist System into Heart, Percutaneous Endoscopic Approach
02HA4RZ	Insertion of External Heart Assist System into Heart, Percutaneous Endoscopic Approach
02RK4JZ	Replacement of Right Ventricle with Synthetic Substitute, Percutaneous Endoscopic Approach
02RL0JZ	Replacement of Left Ventricle with Synthetic Substitute, Open Approach
02RL4JZ	Replacement of Left Ventricle with Synthetic Substitute, Percutaneous Endoscopic Approach
02UA0JZ	Supplement Heart with Synthetic Substitute, Open Approach
02UA3JZ	Supplement Heart with Synthetic Substitute, Percutaneous Approach
02UA4JZ	Supplement Heart with Synthetic Substitute, Percutaneous Endoscopic Approach
02WA0JZ	Revision of Synthetic Substitute in Heart, Open Approach
02WA0QZ	Revision of Implantable Heart Assist System in Heart, Open Approach
02WA3QZ	Revision of Implantable Heart Assist System in Heart, Percutaneous Approach
02WA3RZ	Revision of External Heart Assist System in Heart, Percutaneous Approach
02WA4QZ	Revision of Implantable Heart Assist System in Heart, Percutaneous Endoscopic Approach
5A02116	Assistance with Cardiac Output using Other Pump, Intermittent
5A02216	Assistance with Cardiac Output using Other Pump, Continuous

Description

HEART FAILURE

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1, 3, and 5 years of about 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Treatment

Ventricular Assist Devices

Implantable ventricular assist devices (VADs) are attached to the native heart, which may have enough residual capacity to withstand a device failure in the short term. In reversible heart failure conditions, the native heart may regain some function, and weaning and explanting of the mechanical support system after months of use has been described. VADs can be classified as internal or external, electrically or pneumatically powered, and pulsatile or continuous-flow. Initial devices were pulsatile, mimicking the action of a beating heart. More recent devices may use a pump, which provides continuous flow. Continuous devices may move blood in a rotary or axial flow.

At least 1 VAD system developed is miniaturized and generates an artificial pulse, the HeartMate 3 Left Ventricular Assist System.

Surgically implanted VADs represent a method of providing mechanical circulatory support for patients not expected to survive until a donor heart becomes available for transplant or for whom transplantation is contraindicated or unavailable. VADs are most commonly used to support the left ventricle, but right ventricular and biventricular devices may be used. The device is larger than most native hearts, and therefore the size of the patient is an important consideration; the pump may be implanted in the thorax or abdomen or remain external to the body. Inflow to the device is attached to the apex of the failed ventricle, while outflow is attached to the corresponding great artery (aorta for the left ventricle, a pulmonary artery for the right ventricle). A small portion of the ventricular wall is removed for insertion of the outflow tube; extensive cardiotomy affecting the ventricular wall may preclude VAD use.

Total Artificial Hearts
Initial research into mechanical assistance for the heart focused on the total artificial heart (TAH), a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in 2 patients but is currently experimental.

Percutaneous VADs
Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Some circulatory assist devices are placed percutaneously (ie, are not implanted). They may be referred to as percutaneous VADs (pVADs). A pVAD is placed through the femoral artery. Two different pVADs have been developed, the TandemHeart and the Impella device. In the TandemHeart System, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

Summary

Ventricular Assist Device
For individuals who have end-stage heart failure who receive a VAD as a bridge to transplant, the evidence includes single-arm trials and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life (QOL), and treatment-related mortality and morbidity. There is a substantial body of evidence from clinical trials and observational studies supporting implantable VADs as a bridge to transplant in patients with end-stage heart failure, possibly improving mortality as well as QOL. These studies have reported that substantial numbers of patients have survived to transplant in situations in which survival would not be otherwise expected. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes a trial and multiple single-arm studies. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. A well-designed trial, with 2 years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for heart transplant. Despite an increase in adverse events, both mortality and QOL appear to be improved for these patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Total Artificial Heart
For individuals who have end-stage heart failure who receive a TAH as a bridge to transplant, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, based on the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL,

and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Percutaneous Ventricular Assist Device
For individuals with cardiogenic shock or who undergo high-risk cardiac procedures who receive a percutaneous VAD (pVAD), the evidence includes randomized controlled trials. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four randomized controlled trials of pVAD vs intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates associated with pVAD use. Another randomized controlled trial comparing pVAD with IABP as an adjunct to high-risk percutaneous coronary interventions was terminated early due to futility; analysis of enrolled subjects did not demonstrate significant improvements in the pVAD group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock refractory to IABP who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
1/2019	Clarified coding information.
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
1/2018	Clarified coding information.
10/2017	BCBSA National medical policy review. Policy statements were reordered; wording of statements unchanged. 10/1/2017
10/2016	New references added from BCBSA National medical policy.
7/2015	New references added from BCBSA National medical policy.
7/2014	New references added from BCBSA National medical policy. Coding information clarified.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015. Coding information clarified.
8/2013	BCBSA National medical policy review. Policy statement on children amended; age range changed from 5-16 to 0-16. Effective 8/1/2013.
1/2013	Updated to add new CPT codes 33990-33993.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
1/2011	New policy, posted 1/2011. Same information removed from policy #388, Total Artificial Hearts and Ventricular Assist Devices.
4/2010	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2009	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.
4/2007	Reviewed - Medical Policy Group - Cardiology. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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