MASSACHUSETTS

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Medical Policy

Total Artificial Hearts and Implantable Ventricular Assist Devices

Table of Contents

Policy Number: 280

BCBSA Reference Number: 7.03.11 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

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

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Long-Term Devices

Destination Therapy

Implantable VADs with FDA approval or clearance may be considered **MEDICALLY NECESSARY** as destination therapy with end-stage heart failure adult patients who meet the following criteria:

- New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV;
- Left ventricular ejection fraction ≤ 25%;
- Inotrope-dependent; OR cardiac index <2.2 liters/min/m^2, while not on inotropes and also meeting one of the following:
    - On optimal medical management, based on current heart failure practice guidelines for at least 45 of the last 60 days and are failing to respond **OR**
    - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.

Short-Term Devices

Bridge to Transplantation

Implantable ventricular assist devices (VADs) with U.S Food and Drug Administration (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 (VADs) with FDA approval or clearance, including humanitarian device exemptions, 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 (TAHs) 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.

Postcardiotomy Setting/Bridge to Recovery
Implantable VADs with FDA approval 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 VADs or TAHs are considered **INVESTIGATIONAL**, including, but not limited to, the use of TAHs as destination therapy.

The use of non-FDA approved or cleared implantable VADs or TAHs is considered **INVESTIGATIONAL**.

Percutaneous VADs are considered **INVESTIGATIONAL** for all indications.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.
Medicare HMO Blue℠	This procedure is performed in the inpatient setting.
Medicare PPO Blue℠	This procedure is performed in the inpatient setting.

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 medical necessity criteria MUST 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; 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 transseptal puncture
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
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
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
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

According to a 2022 report from the American Heart Association and based on data collected from 2015 to 2018, roughly 6 million Americans ages 20 years or older had heart failure during that time frame.[1] Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years).[2] Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socio-economic status.

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.[3] The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Devices and Regulatory Status

A number of implantable ventricular assist devices (VADs) and artificial heart systems have been FDA approved through a Humanitarian Device Exemption, 510(k), or premarket approval regulatory pathway. This section discusses currently marketed devices.

FDA maintains a list of recent device recalls at https://www.fda.gov/medical-devices/medical-device-recalls/2021-medical-device-recalls

Ventricular Assist Devices

Implantable 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.

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.

The intent of treatment may evolve over the course of treatment; for example, there is not necessarily a strict delineation between bridge to transplant and destination therapy, and transplant eligibility can change.

Table 1 lists the VADs currently available in the US. The HeartWare VAD System was discontinued in June 2021 due to evidence from observational studies demonstrating a higher frequency of neurological adverse events and mortality with the system compared to other commercially available LVADs.

Table 1. Available Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, HDE or 510(k) No.	Indication
Thoratec IVAD	Thoratec	Aug 2004	PMA Supp	P870072	Bridge to transplant and postcardiotomy
DeBakey VAD Child	MicroMed	Feb 2004	HDE	H030003	Bridge to transplant in children 5-16 y
HeartMate II	Thoratec	Apr 2008	PMA	P060040	Bridge to transplant and destination
CentriMag	Thoratec	Dec 2019	PMA	P170038	Postcardiotomy, bridge to decision
Berlin Heart EXCOR Pediatric VAD	Berlin	Jun 2017	PMA	P160035	Bridge to transplant
HeartMate 3 Left Ventricular Assist System	Thoratec	Aug 2017 Oct 2018	PMA PMA	P160054 P160054/S008	Bridge to transplant Destination

FDA: U.S. Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval; VAD: ventricular assist device.

Total Artificial Heart

The total artificial heart (TAH)is a biventricular device that completely replaces the function of the diseased heart. An internal battery requires 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.

Currently the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 2). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006 but is no longer being marketed or in development.

Table 2. Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	PMA No.	Indication
SynCardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

Percutaneous Ventricular Assist Devices

Some circulatory assist devices are placed percutaneously (i.e., are not implanted). They may be referred to as pVADs. Two different pVADs have been developed, the TandemHeart and the Impella device (Table 3). 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. 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. 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.

Table 3. Available Percutaneous Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, 510(k) No.	Indication
TandemHeart	Cardiac Assist	Sep 2011	510(k)	K110493	Temporary left ventricular bypass of ≤6 h
Impella Recover LP 2.5	Abiomed	May 2008	510(k)	K063723	Partial circulatory support using extracorporeal bypass control unit for ≤6 h
Impella 2.5 System	Abiomed	Mar 2015	PMA	P140003	Temporary ventricular support for ≤6 h

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

Summary

A ventricular assist device (VAD) is mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Summary of Evidence

Ventricular Assist Device

For individuals who have end-stage heart failure who receive a VAD as a bridge to transplant, the evidence includes a randomized controlled trial, single-arm trials, and observational studies. Relevant outcomes are overall survival (OS), 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 reducing mortality as well as improving 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 an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes randomized controlled trials and multiple single-arm studies. Relevant outcomes are OS, 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 a heart transplant. Despite an increase in adverse events, both mortality and QOL appear to be improved for these patients. A more recent trial comparing VADs has broader inclusion criteria and supports that criterion move away from use of transplant ineligibility, as treatment may evolve over the course of treatment. The evidence is sufficient to determine that the technology results in an 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 OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given 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 an 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 OS, 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 that the technology results in an improvement in the net health outcome.

Percutaneous Ventricular Assist Device

For individuals with cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes randomized controlled trials (RCTs), observational studies, and a systematic review. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD versus intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies and a long-term follow-up study were consistent with the RCT evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes RCTs, observational studies, and systematic reviews of these trials. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Randomized controlled trials, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. Additionally, 2 nonrandomized studies have compared ventricular tachycardia (VT) ablation with pVAD or IABP. Both studies demonstrated that patients who had pVAD support spent less time in unstable VT than patients without pVAD support. However, the current evidence does not support conclusions about the use of pVAD for VT ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cardiogenic shock refractory to intra-aortic balloon pump therapy who receive a pVAD, the evidence includes case series. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to intra-aortic balloon pump 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 that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
10/2022	Annual policy review. References added and updated. Minor editorial refinements to policy statements; intent unchanged.
10/2021	Annual policy review. Evidence review revised substantially to increase clarity. Policy statement revised to remove outdated eligibility criteria, but intent unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
1/2021	Clarified coding information.
10/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Clarified coding information.
10/2017	Annual policy review. Policy statements were reordered; wording of statements unchanged.
10/2016	Annual policy review. New references added.
7/2015	Annual policy review. New references added.
7/2014	Annual policy review. New references added. Coding information clarified.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015. Coding information clarified.
8/2013	Annual 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.

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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