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Medical Policy Manual

Topic: Ventricular Assist Devices and Total Artificial Hearts

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Ventricular Assist Devices (VADs)

Biventricular (BiVADs), Right Ventricular (RVAD), and Left Ventricular (LVADs) Devices

Surgically implanted ventricular assist devices (VADs) are attached to the native heart and vessels to provide temporary mechanical circulatory support by augmenting cardiac output. LVADs to support the left ventricle are the most commonly used VADs, but right ventricular and biventricular devices may also be used. LVADs are most commonly used as a bridge to transplantation for those patients who are not expected to survive without mechanical support until a heart becomes available. LVADs may also be used as a bridge to recovery in patients with reversible conditions affecting cardiac output (e.g., post-cardiotomy cardiogenic shock). More recently, given the success of LVADs for prolonged periods of time, there has been interest in using LVADs as permanent "destination" therapy for patients with end-stage heart disease who are not candidates for human heart transplantation due to age or other comorbidities.

Percutaneous Ventricular Assist Devices (pVADs) (Circulatory Assist Devices)

pVADs have been developed for short-term use in patients who require acute circulatory support. These devices are placed through the femoral artery. Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™), and the Impella® device (AbioMed™). In the TandemHeart™ system, a catheter is introduced through the femoral artery 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 also introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is 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 (MI), stroke, and arrhythmias. There are several situations in which pVADs may offer possible benefits:

- cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP)
- cardiogenic shock, as an alternative to IABP
- high-risk patients undergoing invasive cardiac procedures who need circulatory support.

Total Artificial Hearts (TAHs)

The total artificial heart replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. TAHs may be implanted temporarily as a bridge to heart transplantation or permanently as destination therapy in those who are not candidates for transplantation. The currently available temporary TAH is the CardioWest™ Total Artificial Heart which is used in the inpatient hospital setting as a bridge to heart transplantation. The CardioWest TAH is implanted after the native ventricles have been excised.

The AbioCor® Implantable Replacement Heart is a permanent TAH currently available as destination therapy for people who are not eligible for a heart transplant and who are unlikely to live more than a month without intervention. The device has an internal battery that allows the recipient to be free from all external connections for up to one hour. The system also includes two external batteries that allow free movement for up to two hours. During sleep and while batteries are being recharged, the system can be plugged into an electrical outlet. In order to receive the AbioCor artificial heart, in addition to meeting other criteria, patients must undergo a screening process to determine if their chest volume is large enough to hold the two-pound device which is too large for about 90% of women and for many men.

Regulatory Status

Device Name	Device Type	Manufacturer	FDA Approval	Indication
HeartMate II®	LVAD	Thoratec Corp.	PMA	Bridge to transplant and destination therapy
Thoratec® IVAD	BiVAD	Thoratec Corp.	PMA + Supplement	Bridge to transplant and post-cardiotomy
Levitronix Centrimag®	RVAD	Levitronix, LLC	HDE	Postcardiotomy (temporary circulatory support for up to 14 days)
Novacor®	LVAD	World Heart, Inc.	PMA	Bridge to transplant
DeBakey VAD® Child	LVAD	MicroMed Technology, Inc.	HDE	Bridge to transplant in children 5-16 years of age
EXCOR® Pediatric System	BiVAD	Berlin Heart, Inc.	HDE	Bridge to transplant, pediatric (newborns to teens)
Jarvik 2000	LVAD	Jarvik Heart, Inc.	*IDE-Investigational*†	
HeartWare® Ventricular Assist System (HVAD®)	VAD	Heartware Intl., Inc.	PMA	Bridge to transplant – for use in-hospital or out-of-hospital
Impella® Recover LP 2.5	pVAD	Abiomed, Inc.	510(k)	Partial circulatory support using an extracorporeal

				bypass control unit for periods up to 6 hours
TandemHeart®	pVAD	CardiacAssist, Inc.	510(k)	Temporary left ventricular bypass of six hours of less
SynCardia Temporary TAH (formerly called CardioWest™)	Temporary total artificial heart	SynCardia Systems, Inc.	510(k)	Bridge to transplant – for use inside the hospital
AbioCor® TAH	Implantable Replacement Heart System	AbioMed, Inc.	HDE	Destination therapy

†FDA Investigational Device Exemption (IDE) is not considered a full FDA approval. Devices with an IDE designation are considered investigational.

MEDICAL POLICY CRITERIA

I. Implantable ventricular assist devices (i.e., LVADs, RVADs and BiVADs)

A. Implantable ventricular assist devices with FDA PMA, 510(k), or HDE clearance may be considered **medically necessary** for any of the following indications (1-3):

1. As a bridge to transplantation for patients who meet all of the following criteria:

a. Currently listed as a heart transplantation candidate or undergoing evaluation to determine candidacy for heart transplantation

b. Not expected to survive until a donor heart can be obtained

2. For use in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

3. As destination therapy in patients meeting all of the following criteria:

a. End-stage heart failure

b. Documented ineligibility for human heart transplantation

c. One of the following criteria is met:

i. New York Heart Association (NYHA) class III or IV* for at least 28 days who have received at least 14 days support with an intraaortic balloon pump or are dependent on intravenous inotropic agents, with two failed weaning attempts

ii. NYHA class IV* heart failure for at least 60 days.

* NYHA Class III = marked limitation of physical activity; less than ordinary activity leads to symptoms

NYHA Class IV = inability to carry on any activity without symptoms; symptoms may be present at rest

B. Ventricular assist devices are considered **investigational** in all other circumstances, including but not limited to the following:

1. Use of a non-FDA approved ventricular assist device.

2. Percutaneous ventricular assist devices (pVADs)

II. Total Artificial Hearts

A. Total artificial hearts with FDA PMA, 510(k), or HDE clearance may be considered **medically necessary** as a bridge to heart transplantation in patients meeting all of the following criteria:

1. Has biventricular failure

2. Currently listed as heart transplantation candidate or undergoing evaluation to determine candidacy for heart transplantation

3. Not considered a candidate for a univentricular or biventricular support device

4. Have no other reasonable medical or surgical treatment options

5. Not expected to survive until a donor heart can be obtained

B. Total artificial hearts are considered **investigational** in all other circumstances, including but not limited to the following:

1. Use as destination therapy

2. Use of a total artificial heart that does not have FDA PMA, 510(k), or HDE clearance

SCIENTIFIC EVIDENCE[1]

The principal outcome associated with treatment of refractory heart failure (HF) is to prolong survival, either temporarily as a bridge to decision, recovery, or heart transplantation, or permanently as a replacement for the damaged heart in patients who are not candidates for heart transplantation.

Ventricular Assist Devices

Bridge to Transplantation Left Ventricular Assist Devices (LVADs)

Technology Assessment

This policy was initially based on a 1996 BlueCross BlueShield Association Technology Evaluation Center (TEC) assessment[2], which concluded that left ventricular assist devices (LVADs) can provide an effective bridge to transplantation. The TEC assessment concluded that patients receiving a VAD showed both higher survival rates to transplantation and higher one-year post-transplant survival compared to patients who did not receive the device. In addition, overall function as reflected by NYHA classification was improved drastically during the period of LVAD support. Although certain adverse effects were more frequent among LVAD recipients (e.g., thromboembolism, infections), the superior survival to transplant, post-transplant survival and NYHA status suggest that overall, patients who receive LVADs have better health outcomes than patients who do not receive them.

Systematic Reviews

A systematic review published in 2011 supported the conclusions reached in the TEC assessment.[3] This review included 31 observational studies that compared outcomes of transplant in patients who did and did not have pre-transplant LVAD. Survival at one year was more likely in patients who had LVAD treatment, but this benefit was confined to patients who received an intra-corporeal device (relative risk [RR]: 1.8, 95% confidence interval [CI]: 1.53-2.13). For patients treated with an extracorporeal device, the likelihood of survival was not different from patients who were not treated with an LVAD (RR: 1.08, 95% CI: 0.95-1.22). There was no difference in the risk of rejection between patients who did and did not receive LVAD treatment.

Clinical Trials

Additional reports not included in the 1996 TEC assessment or the 2011 systematic review are consistent with the above analysis.[4-6] Recent evidence also suggests that the HeartMate II axial achieves similar or better results than the earlier pulsatile HeartMate I model. In six reports with samples ranging from 32 to 279 patients, most participants received the new device as a bridge to transplantation.[7-12] Survival rates at six months and one year were 67-87%, and 50-80%, respectively. These rates are similar to those observed in a recent report of a federal circulatory support device registry.[13] One report, however, compared HeartMate I and HeartMate II recipients at a single center, finding the same 1-year survival and similar rates of subsequent development of right heart failure (HF).[9] Serious adverse events occurring after HeartMate II implantation included bleeding episodes requiring reoperation, stroke, infection, and device failure. A European study that included 67 bridge to transplant patients and 31 destination therapy patients found similar 1-year survival rates in the two groups: 63% and 69%, respectively.

It should be recognized that left ventricular assist devices cannot change the number of patients undergoing heart transplantation due to the fixed number of donor hearts. However, the LVAD will categorize its recipient as a high priority heart transplant candidate. Currently available LVADs consist of pulsatile devices that require both stiff power vent lines that perforate the skin and bulky implantable pump chambers. There is considerable research interest in developing non-pulsatile axial flow systems that have the potential for small size and low-noise levels.[14-19]

Publications on children using VADs as a bridge to transplantation have reported positive outcomes. For example, Davies and colleagues reported that pediatric patients requiring a pretransplantation VAD had similar long-term survival to those not receiving mechanical circulatory support.[20]

Bridge to Recovery

Post-Cardiotomy VADs

VAD support was originally indicated for the treatment of postcardiotomy cardiogenic shock in patients who could not be weaned from cardiopulmonary bypass. VAD use in this setting is temporary and brief, lasting between 1.4 and 5.7 days. The overall salvage rate for this indication is low, at approximately 25 percent; however, without VAD support, patients with refractory postcardiotomy cardiogenic shock would experience 100 percent mortality.[6,21,22]

Six studies using the Centrimag RVAD included between 12 and 32 patients, the majority of whom received biventricular devices.[22-27] Indications and numbers of patients in these five studies were: support for post-cardiotomy cardiogenic shock (bridge to recovery), bridge to long-term device implantation (n=9), treatment of right heart failure in patients who previously received LVADs, bridge to later decision when neurologic status is clarified, and acute donor graft failure. The mean time on mechanical circulatory support ranged from 9.4 days to 46.9 days. The 30-day mortality rates were between 17% and 63%. The proportion of patients discharged

from the hospital was between 30% and 83%. Major complications included bleeding requiring reoperation, sepsis, and stroke. No device failures were observed in these studies.

LVADs as Destination Therapy

Technology Assessment

The policy statement regarding LVADs as destination therapy was initially based on a 2002 TEC assessment[28] that offered the following observations and conclusions:

- The available evidence comes from a single, well-designed and rigorously conducted randomized trial, known as the REMATCH study.[29] The study was a cooperative effort of Thoratec, Columbia University and the National Institutes of Health.

- The randomized trial found that patients with end-stage heart failure who are not candidates for cardiac transplantation have significantly better survival on an LVAD compared with treatment by optimal medical therapy. Median survival was improved by approximately 8.5 months. Serious adverse events were more common in the LVAD group, but these appear to be outweighed by this group's better outcomes on function. NYHA Class was significantly improved, as was quality of life among those living to 12 months.

- LVAD patients spend a greater relative proportion of time inside the hospital than medical management patients do, but the survival advantage would mean a longer absolute time outside the hospital.

Clinical Trials

Updated literature reviews identified no new studies which alter the conclusions reached above. Park and colleagues published a further follow-up of patients in the REMATCH trial, which found that survival and quality of life benefits were still apparent with extended 2-year follow-up.[30] In addition, this study and other case series suggest continuing improvement in outcomes related to ongoing improvements in the device and in patient management.[31] However, the durability of the HeartMate device used in the REMATCH trial is a concern; for example, at one participating institution, all 6 long-term survivors required device change-outs. Next generation devices consisting of smaller continuous flow devices are eagerly anticipated.

Percutaneous Ventricular Assist Devices (pVADs)

Alternative to intra-aortic balloon pump (IABP) in Cardiogenic Shock

- Three randomized controlled trials (RCTs) compared pVAD to IABP in patients with cardiogenic shock.[32-34] In addition, a systematic review and meta-analysis of these three trials have also been published.[35] Per the 2009 meta-analysis by Chen et al., the three RCTs enrolled a total of 100 patients, 53 treated with a pVAD and 47 treated with an IABP. All three study populations included patients with acute MI and cardiovascular shock; one of the trials[34] restricted this population to patients who were post-revascularization in the acute MI setting. The primary outcomes reported were 30-day mortality, hemodynamic measures of LV pump function, and adverse events.

  None of the three trials reported an improvement in mortality associated with pVAD use. The combined analysis estimated the relative risk for death in pVAD patients as 1.06 (95% CI 0.68-1.66, p=0.80). All three trials reported an improvement in LV hemodynamics in the pVAD group. On combined analysis, there was a mean increase in cardiac index of 0.35 L/min/m2 for the pVAD group, an increase in mean arterial pressure of 12.8mm Hg (95% CI 3.6-22.0, p<0.001), and a decrease in pulmonary capillary wedge pressure of 5.3mm Hg (95% CI 1.2-9.4, p<0.05). Complications were more common in the pVAD group. On

combined analysis, patients in the pVAD group had a significantly increased likelihood of bleeding events with a relative risk of 2.35 (95% CI 1.40-3.93). Leg ischemia was also more common in the pVAD group, but this difference did not meet statistical significance (relative risk [RR] 2.59, 95% CI 0.75-8.97, p=0.13).

- Published case series and registry data have reported high success rates with pVAD as an alternative to IABP as a bridge to alternative therapies.[36-38] However, these studies are considered unreliable due to methodological limitations including but not limited to the lack of randomized treatment allocation and the lack of an adequate comparison group.

Bridge to Recovery in Cardiogenic Shock Refractory to IABP

Case series of patients with cardiogenic shock refractory to IABP who were treated with pVAD have also been published. In the largest series, Kar et al. treated 117 patients who had severe, refractory cardiogenic shock with the TandemHeart® System.[39] Eighty patients had ischemic cardiomyopathy and 37 had nonischemic cardiomyopathy. There were significant improvements in all hemodynamic measures following LVAD placement. For example, cardiac index increased from 0.52+0.8L/min/m2 to 3.0+0.9L/min/m2 ($p<0.001$) and the systolic BP increased from 75+15mm Hg to 100+15mm Hg ($p<0.001$). Complications were common post LVAD implantation. Thirty-four patients had bleeding around the cannula site (29.1%) and 35 developed sepsis during the hospitalization (29.9%). Groin hematoma occurred in 6 patients (5.1%); limb ischemia in 4 patients (3.4%); femoral artery dissection or perforation in 2 patients (1.7%); stroke in 8 patients (6.8%); coagulopathy in 13 patients (11.0%).

High-Risk Patients Undergoing Invasive Cardiovascular Procedures

- The PROTECT trial intended to evaluate whether the Impella® 2.5 system improved outcomes for patients undergoing high-risk percutaneous coronary intervention (PCI) procedures.[40] PROTECT I was a feasibility study of 20 patients who had left main disease or last patent coronary conduit that required revascularization, but who were not candidates for coronary artery bypass graft (CABG) surgery. High-risk PCI was performed using the Impella® system for circulatory support. All of the procedures were completed successfully without any hemodynamic compromise during the procedures. There were two patient deaths within 30 days (10%) and two patients had a periprocedural MI (10%). An additional two patients had evidence of hemolysis, which was transient and resolved without sequelae.

- The PROTECT II trial was planned as an RCT to compare the Impella® system with IABP in patients undergoing high-risk PCI procedures. Enrollment was planned for 654 patients from 50 clinical centers. The primary end-point was the composite of 10 different complications occurring within 40 days of the procedure, with the authors hypothesizing a 10% absolute decrease in the complication rate for patients in the pVAD group. The trial was discontinued prematurely in late 2010 due to futility, after an interim analysis revealed that the primary endpoint could not be reached. At this point, approximately half the planned patients had been enrolled. Interim results were presented at the 2011 American College of Cardiology (ACC) scientific meeting.[41] These results reported composite adverse event rates of 38% in the pVAD group compared to 43% in the IABP group (p=0.40).

Other studies are limited to case series[42,43], registry data[44], and a retrospective analysis.[45] While these studies have reported feasibility and promising outcomes for this use of pVADs, randomized comparative trials are needed to validate these results.

<u>Continuous Flow versus Pulsatile Flow VADs</u>

The evidence on the comparative efficacy of different devices consists of one RCT and several non-randomized comparative studies. The RCT reported fairly large differences in a composite outcome measure

favoring the continuous flow devices, with increases in revision and reoperation rates for the pulsatile device group being the largest factor driving the difference in outcomes. Other non-randomized comparative studies, including one database study with large numbers of patients, have not reported important differences between devices on clinical outcomes. The following is a summary of those studies.

In December 2009, Slaughter and colleagues published data from an unblinded randomized multicenter trial.[46] Subjects were randomized to continuous-flow or pulsatile-flow devices on a 2:1 block-randomization basis. The primary outcome measured was a composite endpoint of 2-year survival, free of disabling stroke or need for device replacement. Continuous-flow patients (n=134) reached the primary outcome at a rate of 46% (95% confidence interval [CI] 38-55) compared to pulsatile-flow patients (n=66) rate of 11% (95% CI 3-18), which was a significant difference ($p<0.001$). Analysis of constituent factors indicated that a lower rate of devices needing replacement in the continuous-flow group had the largest effect on the composite endpoint; 2-year death rate also favored this device (58% vs. 24%, $p=0.008$). Stroke and death (within 2 years of implantation) were similar in the 2 groups (stroke rate 12% and death rate 36%). Quality of life scores were also similar in the 2 groups. Although unblinded, this randomized trial adds to the evidence favoring continuous-flow devices.

Nativi et al. published a non-randomized comparison of pulsatile versus continuous flow devices using data from the registry of the International Society for Heart and Lung Transplantation on 8,557 patients undergoing transplant.[47] Comparisons were made among patients receiving a pulsatile LVAD, a continuous flow LVAD, and no LVAD. Two time periods were used for analysis, the first was pre-2004, when nearly all LVADs were pulsatile devices, and post-2004 when continuous use devices began to be used in clinical care. Comparing the first time period to the second time period, there was a significantly greater risk of mortality in the first time period compared to the second time period (relative risk [RR]: 1.30, 95% CI 1.03-1.65, $p=0.03$). When analysis was confined to the second time period, there was no significant improvement in survival for the continuous group compared to the pulsatile group (RR: 1.25, 95% CI: 1.03-1.65, $p=0.03$).

Other non-randomized studies that have compared outcomes from different types of LVADs have been smaller and/or focused on physiologic outcomes.[48-51] In some of these studies, the continuous flow devices exhibit greater improvement in physiologic measures, but none of these studies have reported significant differences between devices in clinical outcomes.

Clinical Practice Guidelines for VADs

American College of Cardiology Foundation/American Heart Association[52,53]

The 2009 focused update of the 2005 ACC/AHA practice guidelines for the management of end-stage heart failure in adults included the following statements related to LVADs:

- LVADs as destination therapy (permanent) may be indicated in a highly select group of patients with refractory end-stage heart failure who are not candidates for heart transplantation and are likely to have an estimated 1-year mortality over 50% with medical therapy alone (Strength of evidence B - based on some conflicting evidence from a single RCT or nonrandomized studies).
- The short-term use of any form of mechanical ventricular support is mentioned as an area of research interest but no recommendation is made regarding this indication.

The Heart Failure Society of America (HFSA)[54]

The HFSA published guidelines in 2010 on surgical approaches to the treatment of heart failure. The guidelines are based on evidence and expert opinion. The following recommendations were made regarding ventricular assist devices:

- Bridge to transplantation: Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant. (Strength of Evidence B - cohort and case-control studies)
- Bridge to recovery: Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a "bridge to decision." These patients should be referred to a center with expertise in the management of patients with advanced HF. (Strength of Evidence C - expert opinion)
- Destination Therapy: Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center. (Strength of Evidence B - cohort and case-control studies)

Total Artificial Hearts

Bridge to Transplantation

In 2004, the CardioWest Total Artificial Heart (now called the SynCardia Total Artificial Heart) received FDA approval for use as a bridge to transplant. The approval was based on the results of a nonrandomized, prospective study of 81 patients.[55] Patients had failed inotropic therapy and had biventricular failure and thus were not considered appropriate candidates for an LVAD. The rate of survival to transplant was 79%, which was considered comparable to the experience with LVAD in patients with left ventricular failure. The mean time from entry into the study until transplantation or death was 79.1 days.

Other case series have been reported on outcomes of the TAH as a bridge to transplant. For example, Copeland et al. reported on 101 patients treated with the SynCardia artificial heart as a bridge to transplant.[56] All patients either met established criteria for mechanically assisted circulatory support, or were failing medical therapy on multiple inotropic drugs. The mean support time was 87 days, with a range of 1-441 days. Survival to transplant was 68.3% (69/101). Of the 32 deaths prior to transplant, 13 were due to multiple organ failure, 6 were due to pulmonary failure, and 4 were due to neurologic injury. Survival after transplant at 1, 5, and 10 years, respectively, was 76.8%, 60.5%, and 41.2%.

Destination Therapy

In currently available studies, the AbioCor Implantable Replacement Heart has only been used as destination therapy for end-stage patients with congestive heart failure. Dowling and colleagues reported on the first seven patients in the AbioCor clinical trial.[57] The 30-day survival rate was 71% compared with the predicted survival rate of 13% with only medical therapy. At 60 days, 43% were still alive and as of July 2006 two patients were still alive, 234 and 181 days postoperatively and remain hospitalized. Deaths were due to intraoperative bleeding at the time of implantation, cerebrovascular accidents, pulmonary embolism, and multiorgan failure. No reports of serious device malfunction have been reported for the seven patients. Frazier and colleagues reported information on four additional patients receiving the AbioCor.[58] Using the same inclusion criteria the device supported three patients for greater than 100 days, whereas a fourth patient expired at 53 days. There were no device related problems reported.

Clinical Practice Guidelines for Total Artificial Hearts

No clinical practice guidelines from U.S. professional associations were found for total artificial hearts.

Summary

Ventricular Assist Devices

The evidence from numerous uncontrolled trials is sufficient to conclude that implantable ventricular assist devices (VADs) as a bridge to transplantation or recovery, or as destination therapy, improve survival in select patients who have no other survival options and would not otherwise be expected to survive. Therefore, implantable VADs may be considered medically necessary when criteria are met.

The evidence on percutaneous ventricular assist devices (pVADs) does not support that these devices improve health outcomes for any indication. Three randomized controlled trials (RCTs) that compared pVAD with intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit, and reported higher complications associated with pVAD use. A moderately large RCT of pVAD support versus usual care in patients undergoing high-risk percutaneous coronary intervention (PCI) procedures was terminated early due to futility. It was determined that the study would not meet the prespecified endpoint of a 10% absolute decrease in complications. The evidence for patients with cardiogenic shock refractory to IABP is limited to case series, which are considered unreliable due to methodological limitations such as lack of randomized treatment assignment and lack of an adequate comparison group. These case series have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series cannot determine if pVAD improves mortality rates, and high rates of complications are reported with pVAD use. Because of the lack of demonstrated benefits in high-quality trials, and the high complication rates reported, the use of pVADs for all indications is considered investigational.

Total Artificial Hearts

The evidence from uncontrolled trials is sufficient to conclude that the use of a total artificial heart (TAH) as a bridge to heart transplantation improves survival and quality of life in patients who are not candidates for implantable ventricular assist devices and would not be expected to survive with other medical or surgical interventions. Therefore, total artificial hearts may be considered medically necessary as a bridge to heart transplantation in select patients.

Current evidence is insufficient to permit conclusions related to the impact on survival, quality of life, and complication rates of total artificial hearts (TAHs) as destination therapy for patients who are not candidates for heart transplantation. Therefore, the use of TAHs as destination therapy is considered investigational.

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CROSS REFERENCES

Surgical Ventricular Restoration, Surgery, Policy No. 149

Heart Transplant, Transplant, Policy No. 02

Heart/Lung Transplant, Transplant, Policy No. 03

CODES	NUMBER	DESCRIPTION
Note: There is no specific code for reporting prolonged extracorporeal percutaneous transseptal ventricular assist device; the appropriate code for reporting this procedure is 33999.		
CPT	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
	0051T	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
	0052T	Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)
	0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit
HCPCS	Q0478 – Q0509	Ventricular assist device accessories, code range