

## ***Ventricular Assist Devices and Total Artificial Hearts***

**Effective:** October 1, 2018

**Next Review:** December 2018

**Last Review:** September 2018

### **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 and total artificial hearts provide mechanical circulation for patients with end-stage heart disease who are waiting for, or cannot survive, a heart transplant.

### **MEDICAL POLICY CRITERIA**

**Notes:** his policy does not address the use of percutaneous ventricular assist devices (pVADs) which may be considered medically necessary.

- 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. (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.)
      - ii. NYHA class IV\* heart failure for at least 60 days. (NYHA Class IV = inability to carry on any activity without symptoms; symptoms may be present at rest)
- B. Ventricular assist devices and aortic counterpulsation devices are considered **investigational** in all other circumstances, including but not limited to the following:
1. Use of a non-FDA approved device.
- 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. Have 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

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

1. [Extracorporeal Membrane Oxygenation \(ECMO\) for the Treatment of Cardiac and Respiratory Failure in](#)

- [Adults](#), Medicine, Policy No. 152
- [Surgical Ventricular Restoration](#), Surgery, Policy No. 149
- [Heart Transplant](#), Transplant, Policy No. 02
- [Heart/Lung Transplant](#), Transplant, Policy No. 03

## BACKGROUND

### VENTRICULAR ASSIST DEVICES (VADS)

#### Biventricular, Right Ventricular, and Left Ventricular Devices

There are three kinds of ventricular assist devices: biventricular (BiVADs), right ventricular (RVAD), and left ventricular (LVADs). 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.

#### Aortic Counterpulsation Devices

Intra-aortic balloon pump (IABP) devices have been developed as a treatment for cardiogenic shock. IABPs consist of a helium-filled balloon placed in the aorta that deflates during cardiac systole to increase forward blood flow. The inflation and deflation of the balloon is computer-controlled, and can be regulated by either a pressure-sensing catheter or an electrocardiogram. These devices have not been FDA approved.

### TOTAL ARTIFICIAL HEARTS

The total artificial heart (TAHs) 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 CardioWest™ Total Artificial Heart is a temporary TAH, 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 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.	<i>IDE- Investigational†</i>	
HeartWare® Ventricular Assist System (HVAD®)	VAD	Heartware Intl., Inc.	PMA	Bridge to transplant – for use in-hospital or out-of-hospital
AutoCat 2 WAVE® IABP System	IABP	Arrow Intl., Inc.	none	
Maquet CS300™ IABP	IABP	Maquet Cardiovascular, LLC	none	
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.

In August 2015, the U.S. Food and Drug Administration (FDA) published a safety communication about serious adverse events with implantable left ventricular assist devices.<sup>[1]</sup> The warning reports:

- Up to 8.4% of patients using the Thoratec HeartMate II have experienced pump thrombosis at three months;
- Up to 28.7% of patients using the HeartWave HVAD have experience one or more strokes over two years; and

- The FDA is aware of bleeding complications related to both the Thoratec HeartMate II and HeartWave HVAD.

Although adverse events have been reported, the FDA recognizes “that LVADs are life-sustaining, life-saving devices for patients with advanced left ventricular heart failure. When used for the currently approved indications in appropriately selected patients, we believe the benefits of these LVADs continue to outweigh the risks”

## EVIDENCE SUMMARY

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

##### Systematic Reviews

A systematic review published in 2011 supported the conclusions reached in the 1996 BCBSA TEC assessment.<sup>[2,3]</sup> The 2011 review included 31 observational studies that compared outcomes of transplant in patients who did and did not have pre-transplant left ventricular assist devices (LVADs). 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.

##### Nonrandomized Studies

###### Adult patients

Additional reports not included in the 1996 TEC assessment or the 2011 systematic review are consistent with the above analysis.<sup>[4-6]</sup> 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.<sup>[7-12]</sup>

In 2016, Grimm compared outcomes for patients based on the duration of LVAD use, using data from the United Network for Organ Sharing database.<sup>[13]</sup> Of the 1,332 included patients, 130 (9.8%) were classified as short duration (< 90 days), 729 (54.7%) were classified as intermediate duration (90-365 days), and 473 (35.5%) were classified as long duration (> 365 days). A greater proportion of patients in the intermediate and long duration groups were considered functionally independent prior to transplantation compared with the short duration patients. There was no difference in 30-day survival, 6-month survival, or 1-year survival

between the groups. Also, despite worse renal function in the intermediate and long term groups, there was no difference between groups in new onset post-transplant renal failure.

Another report by Grimm using the United Network for Organ Sharing database, suggests that patients bridged to transplant with an LVAD have better outcomes than those bridged with TAH or biventricular assist devices.<sup>[14]</sup> Cheng compared BiVAD to TAH outcomes in this database, and found similar wait-list survival between the groups.<sup>[15]</sup>

In 2014, Deo reported no significant differences in outcomes for 37 patients bridged to transplant with a ventricular assisted device (VAD) and 70 patients who underwent a heart transplant directly.<sup>[16]</sup> In 2013, Slaughter reported combined outcomes for patients included in the HeartWare® bridge-to-transplant study.<sup>[17]</sup> The study included 322 patients with heart failure, eligible for heart transplant, who received the HeartWare® (140 patients from the original study; 190 patients in the continue-access protocol) who were monitored to outcome or had completed 180 days of follow-up at the time of this analysis. Survival at 60, 180, and 360 days was 97%, 91%, and 84%, respectively. The most common adverse events were respiratory dysfunction, arrhythmias, sepsis, and driveline exit site infections. Patients generally had improvements in quality of life measures.

In 2012, Aaronson reported results of a multicenter, prospective study of a newer generation LVAD, the HeartWare®, which is a smaller, continuous flow centrifugal device that is implanted in the pericardial space.<sup>[18]</sup> The study enrolled 140 patients who were awaiting heart transplantation who underwent HeartWare® implantation. A control group of 499 subjects was comprised of patients drawn from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database, which collects data on patients who receive FDA-approved durable mechanical circulatory support devices. The study's primary outcome was defined as survival on the originally implanted device, transplantation, or explantation for ventricular recovery at 180 days. Secondary outcomes were comparisons of survival between groups and functional, quality of life, and adverse event outcomes in the HeartWare® group. Success occurred in 90.7% of the HeartWare® group and 90.1% of controls ( $P < 0.001$ , noninferiority with a 15% margin). Serious adverse events in the HeartWare® group included, most commonly, bleeding, infections, and perioperative right heart failure.

Evidence 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.<sup>[19-24]</sup> Survival rates at six months and one year were 67-87%, and 50-80%, respectively. These rates are similar to those reported from INTERMACS.<sup>[25]</sup> An additional report from INTERMACS comparing the HeartMate II to other LVAD devices for patients who received them with a bridge to transplantation indication reported that 80% and 91% of HeartMate II and other LVAD patients reached transplant, cardiac recovery, or ongoing LVAD support by six months.<sup>[26]</sup> One report, however, compared HeartMate I and HeartMate II recipients at a single center, finding the same one year survival and similar rates of subsequent development of right heart failure.<sup>[21]</sup> 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 one year survival rates in the two groups: 63% and 69%, respectively. A report on HeartMate II recipients at a single institution found that out of 250 LVAD patients between November 2011 and June 2016, 6% (16) required a device pump exchange during the study period, and all but one patient survived until hospital discharge.<sup>[27]</sup>

## Pediatric Patients

Publications on children using VADs as a bridge to transplantation have reported positive outcomes. For example, a retrospective study of all children listed for a heart transplant at a single center between 1993 and 2009 found that mortality dropped significantly after the availability of VADs.<sup>[28]</sup> Davies reported that pediatric patients requiring a pretransplantation VAD had similar long-term survival to those not receiving mechanical circulatory support.<sup>[29]</sup>

In 2013, Almond reported results from a prospective, multicenter registry to evaluate outcomes in children who received the Berlin Heart EXCOR device as a bridge to transplant.<sup>[30]</sup> All patients were followed up from the time of EXCOR implantation until transplantation, death, or recovery. The study included 204 children, 67% of whom received the device under compassionate use. Survival at 12 months on EXCOR support was 75%, including 64% who survived to transplantation, 6% who recovered (device explanted and patient survived 30 days), and 5% alive with the device in place. In a follow-up study which evaluated 204 children from the same registry, Jordan reported relatively high rates of neurologic events in pediatric patients treated with the EXCOR device (29% of patients), typically early in the course of device use.<sup>[31]</sup> A 2016 report on this group included 358 bridge-to-transplant EXCOR patients, and found that short- and mid-term post-transplant survival in these patients was similar to that of patients who did not receive pre-transplant mechanical circulatory support.<sup>[32]</sup>

In 2016, Wehman reported on post-transplant survival outcomes for pediatric patients who received a VAD, extracorporeal membrane oxygenation (ECMO), or no mechanical circulatory support (MCS), in the pre-transplant period.<sup>[33]</sup> The study included 2777 pediatric patients who underwent heart transplant from 2005 to 2012 who were identified through the United Network for Organ Sharing Database, of whom 428 were bridged with VADs and 189 were bridged with ECMO. In unadjusted analysis, the actuarial 5-year survival was highest in the direct-to-transplant group (77%), followed by the VAD group (49%) and then the ECMO group (35%). In a proportional hazards model to predict time to death, restricted to the first 4 months post-transplant, ECMO bridging was significantly associated with higher risk of death (adjusted hazard ratio [HR] 2.77 vs direct-to-transplant, 95% CI 2.12 to 3.61,  $P < 0.0001$ ). However, a model to predict time to death excluding deaths in the first 4 months post-transplant, the bridging group was not significantly associated with risk of death.

## **Section Summary**

In adults, the evidence on the efficacy of LVADs as bridge to transplant consists of numerous nonrandomized studies comparing different LVADs devices among patients who have no other treatment options. In children, the evidence consists of several nonrandomized studies. These studies report that substantial numbers of patients survive the transplant in situations in which survival would not be otherwise expected. Despite the lack of high-quality studies, this evidence is sufficient to determine that outcomes are improved in patients who have no other options for survival.

## **VENTRICULAR ASSIST DEVICES AS BRIDGE TO RECOVERY**

### **Nonrandomized Studies**

Support from VADs 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%; however, without VAD support, patients with refractory postcardiotomy cardiogenic shock would experience 100% mortality.<sup>[6,34,35]</sup> Bulic (2017) identified all U.S. children between 1 and 21 years of age at heart transplant between 2006 and 2015 for dilated cardiomyopathy who were supported with an LVAD or vasoactive infusions alone at the time of heart transplant from the Organ Procurement and Transplant Network registry (n=701).<sup>[36]</sup> Children receiving LVAD were older, on a higher level of hemodynamic support, more likely to be on dialysis and waited long to receive a donor heart than children receiving vasoactive infusions. Functional status as measured by the median Karnofsky Performance Scale at heart transplant was higher for children receiving LVAD compared with vasoactive infusion (6 vs 5, p<0.001) and children receiving LVAD were more likely to be discharged from the hospital at the time of transplant. The percent of children having stroke at the time of transplant was higher in those receiving LVAD (3% vs 1%, p=0.04).

Takayama reported outcomes for a retrospectively defined cohort of 143 patients who received a CentriMag VAD as a “bridge to decision” for refractory cardiogenic shock due to a variety of causes.<sup>[37]</sup> Patients were managed with a bridge-to-decision algorithm. Causes of cardiogenic shock included failure of medical management (n=71), postcardiotomy shock (n=37), graft failure post-heart transplantation (n=2), and right ventricular failure post-implantable LVAD (n=13). The device configuration was biventricular in 67%, isolated right VAD in 26%, and isolated left VAD in 8%. After a mean duration of support of 14 days (interquartile range, 8-26 days), 30% of patients had myocardial recovery, 15% had device exchange to an implantable VAD, and 18% had a heart transplantation.

In 2016, Acharya reported on patients who underwent VAD placement in the setting of acute myocardial infarction (AMI) who were enrolled in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry, a prospective national registry of FDA-approved durable mechanical circulatory support devices.<sup>[38]</sup> Patients who had an AMI as the admitting diagnosis or a major myocardial infarction (MI) as a hospital complication that resulted in VAD implantation (n=502) were compared with patients who underwent VAD implantation for non-AMI indications (n=9727). Patients in the AMI group were generally sicker at baseline, with higher rates of smoking, severe diabetes, and peripheral vascular disease, but had fewer cardiac surgeries and recent cardiovascular hospitalizations. Most AMI patients (53.8%) were implanted with a “bridge-to-candidacy” strategy. At 1 month post VAD, 91.8% of the AMI group were alive with the device in place. At 1 year post-VAD, 52% of the AMI group were alive with the device in place, 25.7% had received a transplant, 1.6% had their VAD explanted for recovery, and 20.7% died with the device in place. Another retrospective study of 15,138 patients in the INTERMACS registry found that the incidence of recovery was significantly higher in bridge-to-recovery patients than in non-bridge-to-recovery patients (11.2% vs 1.2%, p<0.0001).<sup>[39]</sup>

Topkara (2016) reported a similar analysis of 13,454 INTERMACS adults with implants between June 2006 and June 2015 without TAH or pulsatile-flow LVAD or heart transplant.<sup>[40]</sup> Device explant rates for cardiac recovery were 0.9% at 1-year, 1.9% at 2-year, and 3.1% at 3-year follow-up. An additional 9% of patients demonstrated partial cardiac recovery.

In a smaller single-center retrospective cohort study, Mohamedali reported outcomes for 48 patients treated with biventricular support with the CentriMag device as a “bridge to decision”, 18 of whom had biventricular support with venoarterial (VA) extracorporeal membrane oxygenation (ECMO), while the remainder received just biventricular VAD support.<sup>[41]</sup> Overall,



23 patients were explanted, nine to recovery, 14 to a durable LVAD, with three additional patients explanted for withdrawal of care. However, given that the study included patients who received VA ECMO, it is difficult to assess the relative impact of VAD support alone.

Six studies using the Centrimag RVAD included between 12 and 32 patients, the majority of whom received biventricular devices.<sup>[35,42-46]</sup> 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.

In a prospective multicenter study to assess myocardial recovery in patients with LVAD implantation as a bridge to transplant, Maybaum evaluated 67 patients with heart failure who had undergone LVAD implantation for severe heart failure.<sup>[47]</sup> After 30 days, patients demonstrated significant improvements compared with pre-LVAD state in left ventricular ejection fraction (LVEF, 17.1% vs 34.12%,  $p < 0.001$ ), left ventricular end-diastolic diameter (7.1 cm vs 5.1 cm,  $p < 0.001$ ), and left ventricular mass (320 g vs 194 g,  $p < 0.001$ ). However, only 9% of patients demonstrated enough recovery to have their LVAD explanted.

In a 2006 study, a series of 15 patients with severe heart failure due to nonischemic cardiomyopathy underwent implantation of LVADs, along with medical management designed to enhance myocardial recovery.<sup>[48]</sup> Eleven of 15 patients had enough myocardial recovery to undergo LVAD explantation; two patients died after explantation. Among those who survived, the cumulative rate of freedom from recurring heart failure was 100% and 88.9%, respectively, at one and four years post explantation. The same group subsequently reported results of their LVAD explantation protocol among patients with severe heart failure due to nonischemic cardiomyopathy who had nonpulsatile LVADs implanted.<sup>[49]</sup> They included 20 patients who received a combination of angiotensin converting enzyme ACE inhibitors, beta blockers, and adosterol antagonists followed by the  $\beta$ 2-agonist clenbuterol. One patient was lost to follow-up and died after 240 days of support. Of the remaining 19 patients, 12 (63.2%) were successfully explanted after a mean 286 days; estimated survival without heart failure recurrence was 83.3% at one and three years.

### Section Summary

The studies previously outlined indicate that a subset of patients who receive a VAD as a bridge to transplant demonstrate improvements in their cardiac function, sometimes to the point that they no longer require the VAD. However, questions remain about defining and identifying the population most likely to experience cardiac recovery with VAD placement. One clearly defined population in which the potential for myocardial recovery exists is in the postcardiotomy setting. Finally, current evidence is insufficient to allow the identification of other heart failure patient populations who might benefit from the use of a VAD as a specific bridge-to-recovery treatment strategy. Ongoing research studies are addressing this question, along with protocols for transitioning patients off VAD use.

## **LEFT VENTRICULAR ASSIST DEVICES AS DESTINATION THERAPY**

## Technology Assessment

The policy statement regarding LVADs as destination therapy was initially based on a 2002 TEC assessment<sup>[50]</sup> 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.<sup>[51]</sup> 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.

### Randomized Controlled Trials

Park published a further follow-up of patients in the REMATCH trial, mentioned in the above TEC assessment, which found that survival and quality of life benefits were still apparent with extended two year follow-up.<sup>[52]</sup>

### Nonrandomized Studies

In 2014 Jorde published results from an FDA-required postapproval study of the HeartMate II device for destination therapy.<sup>[53]</sup> The study included the first 247 HeartMate II patients identified as eligible for the device as destination therapy, outcomes and adverse events did not differ significantly from those treated in the original trial, which compared patients who received the HeartMate II to earlier generation devices (Slaughter [2009], described below).<sup>[54]</sup> Survival in the postapproval cohort was 82% and 69% at one and two years postoperatively, respectively.

A subsequent prospective observational study comparing LVAD support (n=97) with optimal medical therapy (n=103) for patients with heart failure not requiring inotropes also reported superior survival and health-related quality of life in LVAD-treated patients.<sup>[55]</sup> Twelve-month survival was 80% in the LVAD group, compared with 63% in the best medical therapy group (P=0.022).

In addition, other case series suggest continuing improvement in outcomes related to ongoing improvements in the device and in patient management.<sup>[56]</sup> However, the durability of the HeartMate device used in the REMATCH trial is a concern; for example, at one participating institution, all six long-term survivors required device change-outs. Next generation devices consisting of smaller continuous flow devices are eagerly anticipated.

### Section Summary

The primary evidence on the efficacy of LVADs as destination therapy in patients who are not transplant candidates is from the REMATCH study. This study reported that the use of LVADs led to improvements in survival, quality of life, and functional status.

## **CONTINUOUS FLOW VERSUS PULSATILE FLOW VENTRICULAR ASSIST DEVICES**

Randomized Controlled Trials Two RCTs published in 2017 compared centrifugal continuous-flow circulatory pumps with an axial continuous-flow pump (HeartMate II).<sup>[57,58]</sup> Both trials used a similar composite primary outcome but with different lengths of follow-up. In MOMENTUM3, the composite was defined as survival free of disabling stroke or survival free of reoperation to replace or remove the device at six months after implantation. In ENDURANCE, the composite was defined as survival free from disabling stroke with the originally implanted device at two years. Both trials found the centrifugal device to be noninferior to the axial device with respect to the primary, composite outcome and found the centrifugal device having fewer malfunctions and requiring fewer reoperations. The ENDURANCE trial found an increased risk of death by 2 years (35% vs 26%) that was not statistically significant and significant increases in patients experiencing stroke, sepsis, and right heart failure with the centrifugal vs axial device. Both trials reported similar improvements in functional and QOL outcomes in both groups.

In 2009, Slaughter published data from an unblinded randomized multicenter trial.<sup>[54]</sup> 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; two year death rate also favored this device (58% vs. 24%, p=0.008). Stroke and death (within two years of implantation) were similar in the two groups (stroke rate 12% and death rate 36%). Quality of life scores were also similar in the two groups. Although unblinded, this randomized trial adds to the evidence favoring continuous-flow devices.

### **Nonrandomized Studies**

Dell'Aquila compared outcomes for patients treated with a third-generation continuous flow device, the HeartWare device, with those for patients treated with earlier generation devices in a single-center study.<sup>[59]</sup> Comparison-group patients received either an earlier generation continuous flow device or a pulsatile flow device. Of 287 patients who received VAD support from 1993 to 2012, 52 received a HeartWare device, 76 an earlier generation continuous flow device, and 159 a pulsatile device. Survival was significantly better for patients who received a third-generation device, with 24 months survival of 70.4%, compared with 33.7% for patients who received an earlier generation continuous flow device and 33.8% for patients who received a pulsatile flow device (p=0.013). The difference in survival associated with third generation devices was more pronounced for higher scores on the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACs) scale.

Nativi 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.<sup>[60]</sup> 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.<sup>[61-64]</sup> 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.

## Section Summary

The evidence of the comparative efficacy of centrifugal continuous-flow vs axial continuous-flow devices consists of two RCTs of two different centrifugal continuous-flow devices. The MOMENTUM3 trial compared HeartMate 3 centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as a bridge to transplantation or destination therapy. HeartMate 3 is not currently FDA-approved. The ENDURANCE trial compared HeartWare centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as destination therapy. HeartWare is FDA-approved for bridge to transplantation. Both trials found the centrifugal device to be noninferior to the axial device for the primary, composite outcome including measures of survival, freedom from disabling stroke and freedom from device failure. While there are fewer device failures with the centrifugal devices without significant increase in disabling stroke, the HeartWare device was associated with increased risk of any stroke over a period of two years.

The evidence on the comparative efficacy of continuous-flow vs pulsatile-flow devices consists of one RCT and several nonrandomized 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 nonrandomized comparative studies, including one database study with large numbers of patients, have not reported differences between devices on clinical outcomes.

## AORTIC COUNTERPULSATION DEVICES

Intra-aortic balloon pump (IABP) devices have been developed as a treatment for cardiogenic shock. IABPs consist of a helium-filled balloon placed in the aorta that deflates during cardiac systole to increase forward blood flow. The inflation and deflation of the balloon is computer-controlled, and can be regulated by either a pressure-sensing catheter or an electrocardiogram. These devices have not been FDA approved, and therefore the evidence for these devices is not reviewed in detail.

# TOTAL ARTIFICIAL HEARTS

## BRIDGE TO TRANSPLANTATION

### Nonrandomized Studies

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.<sup>[65]</sup> 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 reported on 101 patients treated with the SynCardia artificial heart as a bridge to transplant.<sup>[66]</sup> 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.

### **Nonrandomized Studies**

Torregrossa reported on 47 patients who received a TAH at 10 worldwide centers and had the device implanted for more than one year.<sup>[67]</sup> Patients were implanted for dilated cardiomyopathy (n=23), ischemic cardiomyopathy (n=15), and “other” reasons (n=9). Over a median support time of 554 days (range, 365-1373 days), 34 patients (72%) were successfully transplanted, 12 patients (24%) died while on device support, and one patient (2%) was still supported. Device failure occurred in five patients (10%). Major complications were common, including systemic infection in 25 patients (53%), driveline infections in 13 patients (27%), thromboembolic events in nine patients (19%) and hemorrhagic events in seven patients (14%). Two of the deaths occurred secondary to device failure

Dowling reported on the first seven patients in the AbioCor clinical trial.<sup>[68]</sup> 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 reported information on four additional patients receiving the AbioCor.<sup>[69]</sup> Using the same inclusion criteria as in the above RCT 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.

## **SECTION SUMMARY**

There is little evidence on the use of TAH as a bridge to transplantation, or as destination therapy, compared with the use of LVADs. The type of evidence on bridge to transplant is similar to that for LVADs (i.e., case series reporting substantial survival rates in patients without other alternatives). Therefore, this evidence is sufficient to conclude that TAH improves

outcomes for these patients similar to LVADs, and is a reasonable alternative for patients who require bridge to transplantation but who are ineligible for other types of support devices. Although TAHs show promise for use as destination therapy in patients who have no other treatment options, the available data on their use is extremely limited. There is insufficient evidence on the use of TAH as destination therapy to support conclusions about the efficacy of TAH in this setting.

## PRACTICE GUIDELINE SUMMARY

### **SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS**

In 2015, the Society for Cardiovascular Angiography and Interventions (SCAI), the Heart Failure Society of America (HFSA), the Society of Thoracic Surgeons (STS), the American Heart Association (AHA), and the American College of Cardiology (ACC) published a clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care.<sup>[70]</sup> This statement addressed intra-aortic balloon pumps (IABPs), left atrial (LA)-to-aorta assist device (eg, TandemHeart), left ventricle (LV)-to-aorta assist devices (eg, Impella), extracorporeal membrane oxygenation (ECMO), and methods of right-sided support. Specific recommendations are not made, but the statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention (PCI), those with cardiogenic shock, and those with acute decompensated heart failure.

### **AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION (ACCF/AHA)<sup>[71]</sup>**

The 2013 ACCF/AHA practice guidelines for the management of heart failure included the recommendations below related to mechanical circulatory support (MCS) which includes LVADs. All of these recommendations were rated II.a., level of evidence B, defined as a recommendation in favor of the treatment being useful, with some conflicting evidence from a single RCT or nonrandomized studies.

- MCS is considered beneficial in carefully selected patients with stage D heart failure with reduced ejection fraction (HFrEF) as a bridge to transplantation or recovery.
- Nondurable mechanical cardiac support including percutaneous and extracorporeal VADs are considered “reasonable” as a bridge to recovery or a bridge to decision for carefully selected patients with HFrEF with acute, profound hemodynamic compromise.
- Durable (permanent) MCS is considered reasonable to prolong survival for carefully selected patients with stage D HFrEF.

The guidelines note that, although optimal patient selection for MCS is an area of investigation, general indications for referral for MCS therapy include patient with LVEF<25% and NYHA class III-IV functional status despite guideline-directed medical therapy (GDMT) including cardiac resynchronization therapy (CRT), when indicated, with either high predicted 1- to 2-year mortality or dependence on continuous parenteral inotropic support.

### **THE HEART FAILURE SOCIETY OF AMERICA (HFSA)**

The HFSA published guidelines in 2010 on surgical approaches to the treatment of heart failure. The guidelines are based on evidence and expert opinion.<sup>[65]</sup> 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)

## SUMMARY

### VENTRICULAR ASSIST DEVICES

There is enough research to show that implantable ventricular assist devices (VADs) as a bridge to transplantation or recovery, or as destination therapy, improve health outcomes in some patients with heart failure who might not otherwise survive. Therefore, implantable VADs may be considered medically necessary when the policy criteria are met.

There is not enough research to show that ventricular assist devices or aortic counterpulsation devices improve health outcomes for people with heart failure or other heart conditions when policy criteria are not met. Therefore, the use of ventricular assist devices or aortic counterpulsation devices when policy criteria are not met is considered investigational.

### TOTAL ARTIFICIAL HEARTS

There is enough research to show that the use of a total artificial heart (TAH) as a bridge to heart transplantation improves survival and quality of life for patients in some specific situations. Therefore, total artificial hearts may be considered medically necessary as a bridge to heart transplantation when policy criteria are met.

There is not enough research to show that total artificial hearts (TAHs) as destination therapy improves health outcomes for patients. Therefore, the use of TAHs as destination therapy is considered investigational.

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## CODES

**Note:** There is no specific code for reporting prolonged extracorporeal percutaneous transeptal ventricular assist device; the appropriate code for reporting this procedure is 33999.

Codes	Number	Description
CPT	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)
	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

<b>Codes</b>	<b>Number</b>	<b>Description</b>
	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
	33999	Unlisted procedure, cardiac surgery
	0451T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; complete system (counterpulsation device, vascular graft, implantable vascular hemostatic seal, mechano-electrical skin interface and subcutaneous electrodes)
	0452T	;aortic counterpulsation device and vascular hemostatic seal
	0453T	;mechano-electrical skin interface
	0454T	;subcutaneous electrode
	0455T	Removal of permanently implantable aortic counterpulsation ventricular assist system; complete system (aortic counterpulsation device, vascular hemostatic seal, mechano-electrical skin interface and electrodes)
	0456T	;aortic counterpulsation device and vascular hemostatic seal
	0457T	;mechano-electrical skin interface
	0458T	;subcutaneous electrode
	0459T	Relocation of skin pocket with replacement of implanted aortic counterpulsation ventricular assist device, mechano- electrical skin interface and electrodes
	0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device, subcutaneous electrode
	0461T	;aortic counterpulsation device
	0462T	Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counterpulsation ventricular assist system, per day
	0463T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day
	<del>0051T</del>	<del>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (Deleted 1/1/2018)</del>
	<del>0052T</del>	<del>Replacement or repair of thoracic unit of a total replacement heart system (artificial heart) (Deleted 1/1/2018)</del>

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<b>Codes</b>	<b>Number</b>	<b>Description</b>
	0053T	Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit (Deleted 1/1/2018)
HCPCS	Q0477 – Q0509	Ventricular assist device accessories, code range

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**Date of Origin:** January 1996