Title: Total Artificial Hearts and Ventricular Assist Devices

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### DESCRIPTION

A ventricular assist device (VAD) is a 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 in those who are not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

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BACKGROUND
Heart failure may be the consequence of a number of differing 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, 5, and 10 years of 88%, 74%, and 55%, respectively. The supply of donor organs has leveled off, while candidates for transplants are increasing, compelling the development of mechanical devices.

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

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

Ventricular Assist Devices
Implantable VADs are attached to the native heart, which may have enough residual activity to withstand a device failure in the short term. In reversible conditions of heart failure, 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 rotary or axial flow.

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

Surgically implanted VADs represent a method of providing mechanical circulatory support for patients not expected to survive until a donor heart becomes available for transplant or for whom transplantation is otherwise 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 left ventricle, pulmonary artery for right ventricle).
A small portion of ventricular wall is removed for insertion of the outflow tube; extensive cardiotomy affecting the ventricular wall may preclude VAD use.

**Percutaneous Ventricular Assist Devices**

Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Some circulatory assist devices are placed percutaneously (ie, are not implanted). These may be referred to as pVADs. pVADs are placed through the femoral artery. Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™; Pittsburgh, PA), and the Impella® device (Abiomed™; Aachen, Germany). 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 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, stroke, and arrhythmias.

There are several situations in which pVADs may offer possible benefits: (1) cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP), (2) cardiogenic shock, as an alternative to IABP, and (3) high-risk patients undergoing invasive cardiac procedures who need circulatory support.

IABPs are outside the scope of this policy.

### REGULATORY STATUS

A number of mechanical circulatory support devices have received approval or clearance for marketing by FDA. These devices are summarized in Table 1, and described further in following sections.

**Table 1. Available Mechanical Circulatory Support Devices**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date of Initial Approval</th>
<th>Method of FDA Clearance</th>
<th>Indication</th>
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<tbody>
<tr>
<td>Thoratec® IVAD</td>
<td>Thoratec</td>
<td>Aug 2004</td>
<td>PMA supplement</td>
<td>Bridge to transplant and postcardiomy</td>
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<tr>
<td>DeBakey VAD® Child</td>
<td>MicroMed</td>
<td>Feb 2004</td>
<td>HDE</td>
<td>Bridge to transplant in children 5-16 y of age</td>
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<tr>
<td>HeartMate II®</td>
<td>Thoratec</td>
<td>Apr 2008</td>
<td>PMA</td>
<td>Bridge to transplant and destination</td>
</tr>
<tr>
<td>Centrimag®</td>
<td>Levitronix (now Thoratec)</td>
<td>Oct 2008</td>
<td>HDE</td>
<td>Postcardiomy</td>
</tr>
<tr>
<td>Berlin Heart EXCOR® Pediatric VAD</td>
<td>Berlin</td>
<td>Dec 2011</td>
<td>HDE</td>
<td>Bridge to transplant</td>
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### Total Artificial Hearts and Ventricular Assist Devices

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<td>HeartWare® Ventricular Assist System</td>
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<td>PMA</td>
<td>Bridge to transplant</td>
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<td>Percutaneous ventricular assist devices</td>
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<tr>
<td>Impella®</td>
<td>Abiomed</td>
<td>May 2008</td>
<td>510(k)</td>
<td>Partial circulatory support using extracorporeal bypass control unit for periods up to 6 h</td>
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<tr>
<td>TandemHeart®</td>
<td>Cardiac Assist</td>
<td>Sep 2005</td>
<td>510(k)</td>
<td>Temporary left ventricular bypass of ≤6 h</td>
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FDA: U.S. Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval.

**Total Artificial Heart**

In October 2004, device CardioWest™ Temporary Total Artificial Heart (SynCardia Systems, Tucson, AZ) was approved by FDA through the premarket approval process (PMA) for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. Also, the temporary CardioWest™ Total Artificial Heart (TAH-t) is intended for use inside the hospital. In April 2010, FDA approved a name change to SynCardia Temporary Total Artificial Heart. FDA product code: LOZ.

In September 2006, the AbioCor® Implantable Replacement Heart System (AbioMed, Danvers MA) was approved by FDA through the HDE process for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who:

- are younger than 75 years of age;
- require multiple inotropic support;
- are not treatable by left ventricular assist device (LVAD) destination therapy; and
- are not weanable from biventricular support if on such support.

In addition to meeting other criteria, patients who are candidates for the AbioCor® TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men. FDA HDE: H040006.

**Ventricular Assist Devices**

In December 1995, the Thoratec® Ventricular Assist Device System (Thoratec Corp., Pleasanton, CA) was approved by FDA through the PMA process for use as a bridge to transplantation in patients suffering from end stage heart failure. The patient should meet all of the following criteria:

- candidate for cardiac transplantation,
- imminent risk of dying before donor heart procurement, and
- dependence on, or incomplete response to, continuous vasopressor support.
In May 1998, supplemental approval for this device was given for the indication for postcardiotomy patients who are unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital in the company of a trained caregiver. In November 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In August 2004, supplemental approval was given to a modified device to be marketed as the Thoratec® Implantable VAD for the same indications. In January 2008, supplemental approval was given to delete Paracorporeal VAD use.

In February 2004, FDA approved the DeBakey VAD® Child under the HDE approval process. According to FDA, this device is indicated under HDE for both home and hospital use for children between the ages of 5 and 16 years who have end stage ventricular failure requiring temporary mechanical blood circulation until a heart transplant is performed.

In April 2008, continuous flow device HeartMate® II LVAS (Thoratec, Pleasanton, CA) was approved by FDA through the PMA process for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The HeartMate II LVAS is intended for use both inside and outside the hospital. In January 2010, the device received the added indication as destination therapy for use in patients with New York Heart Association class III/IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days and are not candidates for cardiac transplantation.

In October 2008, device Centrimag® Right Ventricular Assist Device (Levitronix, Zurich) was approved by FDA under the HDE to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right-sided heart failure.

In December 2011, the Berlin Heart EXCOR® Pediatric VAD was approved via HDE. The indications for this device are pediatric patients with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

In December 2012, FDA approved the HeartWare® Ventricular Assist System (HeartWare, Miami Lakes, FL) through PMA. The device is approved as a bridge to cardiac transplantation in patients at risk for death from refractory end stage left ventricular heart failure.

FDA product code: DSQ.
Percutaneous Ventricular Assist Devices (Circulatory Assist Devices)

In May 2008, the Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) was cleared for marketing by FDA through the 510(k) process for short-term (<6 hours) use in patients requiring circulatory support.

In March 2015, the Impella 2.5 System received approval through the PMA process for temporary ventricular support during high-risk percutaneous coronary interventions.

The TandemHeart® (Cardiac Assist, Pittsburgh) received a similar 510(k) approval for short-term circulatory support in September 2005. FDA product code: KFM.

Several other devices are in clinical trials or awaiting FDA review.
POLICY

A. Postcardiotomy Setting/Bridge to Recovery
1. Implantable ventricular assist devices with U.S. Food and Drug Administration (FDA) approval or clearance may be considered medically necessary in the postcardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

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

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

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

C. Destination Therapy
1. Implantable ventricular assist devices with FDA approval or clearance may be considered medically necessary as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following REMATCH Study criteria:
   a) New York Heart Association (NYHA) class IV heart failure for ≥60 days, OR patients in NYHA class III/IV for 28 days, received ≥14 days’ support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts

2. In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:
   a) Age >65 years; OR
b) Insulin-dependent diabetes mellitus with end-organ damage; OR  
c) Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days); OR  
d) Presence of other clinically significant condition  

D. Percutaneous ventricular assist devices are intended for partial circulatory support for a limited time period. The use of an FDA-approved percutaneous ventricular assist device may be considered **medically necessary** for short-term stabilization of patients with ANY of the following indications:

1. Cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP); OR  
2. Cardiogenic shock, as an alternative to IABP; OR  
3. High-risk patients undergoing invasive cardiac / electrophysiological procedures who need circulatory support (see Policy Guidelines).  

E. Percutaneous ventricular assist devices are considered **experimental / investigational** for all other indications.

F. **Other Indications**  
1. Other applications of implantable ventricular devices or total artificial hearts are considered **experimental / investigational**, including, but not limited to, the use of total artificial hearts as destination therapy.  
2. The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered **experimental / investigational**.

**Policy Guidelines**  
1. Only 2 VADs have approval from FDA for the pediatric population. The DeBakey VAD® Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the HDE process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant, ie, as a bridge to transplant while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.  
2. In general, candidates for bridge-to-transplant implantable VADs are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of less than 2.0 L/min/m while receiving maximal medical support. Patients with VADs are classified by the United Network for Organ Sharing as status I, that is, persons who are most ill and are considered the highest priority for transplant.
3. The median duration for time on the device is between 20 and 120 days.
4. Contraindications for bridge to transplant VADs and TAH include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders, and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or TAH, implantation is also contraindicated in patients with uncorrected valvular disease. See Policy No. 7.03.09 (heart transplantation) for further discussion of heart transplant candidacy.
5. In addition, patients must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest™ temporary Total Artificial Heart, this excludes patients with body surface areas less than 1.7 m² or who have a distance between the sternum and 10th anterior rib of less than 10 cm, as measured by computed tomography scan.
6. High risk patients are defined as patients with a combination of left ventricular dysfunction with an ejection fraction <35% combined with high risk coronary anatomy (severe left main stenosis OR extensive triple vessel coronary disease OR target vessel supplying >40% of the viable myocardium).

RATONALE
This policy is regularly updated with searches of the MEDLINE database. The most recent literature review was performed for the period up to July 11, 2016. The literature review focuses on 3 types of devices: (1) left ventricular assist devices (LVADs), (2) total artificial hearts (TAHs), and (3) percutaneous VADs (pVADs). The literature review addresses short-term use of the devices as a bridge to recovery or transplantation. LVADs and TAHs are also evaluated as longer term destination therapy for patients who are not transplant candidates. Following is a summary of the key literature to date.

Ventricular Assist Devices
VADs as Bridge to Recovery
VADs may have a role in bridging patients to recovery, particularly if there is reverse remodeling of the left ventricle (LV).

In 2016, Acharya et al reported on patients who underwent VAD placement for acute myocardial infarction (AMI) who were enrolled in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry, a prospective national registry of Food and Drug Administration (FDA)–approved durable mechanical circulatory support devices. 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 was 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.
A number of relatively small, noncomparative studies have evaluated left ventricular assist devices (LVADs) as bridge-to-recovery therapy. 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. Eleven of 15 patients had enough myocardial recovery to undergo LVAD explantation; 2 patients died after explantation. Among those who survived, the cumulative rate of freedom from recurring heart failure was 100% and 88.9%, respectively, at 1 and 4 years postexplantation. The same group subsequently reported results of their LVAD explantation protocol among patients with severe heart failure due to nonischemic cardiopathy who had nonpulsatile LVADs implanted. They included 20 patients who received a combination of angiotensin-converting enzyme (ACE) inhibitors, β-blockers, and adosterone antagonists followed by the β₂-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 1 and 3 years. In a prospective multicenter study to assess myocardial recovery in patients with LVAD implantation as a bridge to transplant, Maybaum et al evaluated 67 patients with heart failure who had undergone LVAD implantation for severe heart failure. 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.

Takayama et al 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. 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 postimplantable 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 transplant.

In a smaller single-center retrospective cohort study, Mohamedali et al 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. Overall, 23 patients were explanted, 9 to recovery, 14 to a durable LVAD, with 3 additional patients explanted for withdrawal of care.

Section Summary: VADs as Bridge to Recovery
There has been interest in prospectively identifying subsets of patients who might benefit from a temporary VAD with the goal of bridging to recovery. Available studies have indicated that a subset of patients who receive a VAD as a bridge to transplant or as destination therapy have demonstrated 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. The current evidence is insufficient to allow identification of other heart failure patient populations who might benefit from the use of an LVAD as a specific bridge-to-recovery treatment strategy.
VADs as Bridge to Heart Transplant

**Efficacy**

A 1996 TEC Assessment concluded that VADs can provide an effective bridge to transplantation.\(^9\) Goldstein et al published a more recent review.\(^10\) It should be recognized that VADs do not change the number of patients undergoing heart transplantation due to the fixed number of donor hearts. However, the VAD will categorize its recipient as a high-priority heart transplant candidate.

In 2011, Strueber et al published a case series of 50 patients awaiting heart transplantation treated with HeartWare Ventricular Assist System, which is a smaller, continuous-flow centrifugal device implanted in the pericardial space.\(^11\) Patients were followed until transplantation, myocardial recovery, device explant, or death. The median duration of time on the VAD was 322 days. Nine patients died, 3 from sepsis, 3 from multiple organ failure, and 3 from hemorrhagic stroke. At the end of follow-up, 20 (40%) patients had undergone transplant, 4 (8%) had the pump explanted, and the remaining 17 (34%) continued on pump support. The most common complications were infection and bleeding: 21 (42%) patients had infections and 5 (10%) had sepsis, while 15 (30%) patients had bleeding complications, 10 (20%) of whom required surgery.

In 2012, Aaronson et al reported results of a multicenter, prospective study of a newer generation LVAD, the HeartWare.\(^12\) The study enrolled 140 patients awaiting heart transplantation who underwent HeartWare implantation. A control group of 499 subjects comprised patients drawn from the 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 (QOL), 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.

In 2013, Slaughter et al reported combined outcomes for patients included in the HeartWare bridge-to-transplant study previously described and a continued-access protocol granted by FDA.\(^13\) 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-day follow-up at the time of 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 QOL measures.

In 5 reports published from 2007 to 2008, with sample sizes ranging from 32 to 279 patients, most participants received the continuous-flow device as a bridge to transplantation.\(^14\) Survival rates at 6 months were between 67% and 87%, and between 50% and 80% at 1 year. These rates were similar to those reported from the INTERMACS registry.\(^19\) An additional report from INTERMACS comparing the HeartMate II with other LVADs for patients who received them as a bridge to transplantation reported that 91% and 80% of HeartMate II and other LVAD patients, respectively, reached transplant, cardiac recovery, or ongoing LVAD support by 6 months.\(^20\) A study by Patel et al compared HeartMate I and HeartMate II recipients at a single center, finding...
similar rates of 1-year survival and subsequent development of right heart failure. Serious adverse events occurring after HeartMate II implantation include bleeding episodes requiring reoperation, stroke, infection, and device failure.

**Effects of Pretransplant VADs on Transplant Outcomes**

Published studies continue to report that the use of a VAD does not compromise the success of a subsequent heart transplant and, in fact, may improve posttransplant survival, thus improving the use of donor hearts. A systematic review published in 2011 examined the evidence on the effect of VADs on posttransplant outcomes. This review included 31 observational studies that compared transplant outcomes in patients who did and did not have pretransplant VAD. Survival at 1 year was more likely in patients who had VAD treatment, but this benefit was specific to patients who received an intracorporeal device (relative risk [RR], 1.8; 95% confidence interval [CI], 1.53 to 2.13). For patients treated with an extracorporeal device, the likelihood of survival did not differ from patients not treated with a VAD (RR=1.08; 95% confidence interval [CI], 0.95 to 1.22). There was no difference in the risk of rejection between patients who did and did not receive LVAD treatment.

In 2014, Deo et al reported no significant differences in outcomes for 37 patients bridged to transplant with a VAD and 70 patients who underwent a heart transplant directly. Data from the United Network for Organ Sharing (UNOS), reported by Grimm et al (2016), suggested that patients bridged to transplant with an LVAD have better outcomes than those bridged with TAH or biventricular assist devices.

**Pediatric Patients**

There is 1 FDA-approved device, the EXCOR Pediatric VAD, available for use as a bridge to cardiac transplant in children. FDA approval was based on data from children who were part of the initial clinical studies of this device. Publications have reported positive outcomes for children using VADs as a bridge to transplantation. Using the UNOS database, Davies et al reported on use of VADs in pediatric patients undergoing heart transplantation. Their analysis concluded that pediatric patients requiring a pretransplantation VAD have similar long-term survival to those not receiving mechanical circulatory support.

Following FDA approval, Fraser et al evaluated the EXCOR device among 48 children, ages 16 or younger, with 2-ventricle circulation who had severe heart failure, despite optimized treatment and were listed for heart transplant. Patients were divided into 2 groups based on body surface area (BSA); a historical control group of children, receiving circulatory support with ECMO from the Extracorporeal Life Support Organization registry, were matched in a 2:1 fashion with study participants based on propensity-score matching. For participants in cohort 1 (BSA <0.7 m²), the median survival time had not been reached at 174 days, while in the matched ECMO comparison group, the median survival was 13 days (p<0.001). For participants in cohort 2 (BSA range, 0.7 to <1.5 m²), the median survival was 144 days compared with 10 days in the matched ECMO group (p<0.001). Rates of adverse events were high in both EXCOR device cohorts, including major bleeding (42% and 50% of cohort 1 and cohort 2, respectively), infection (63% and 50% of cohort 1 and cohort 2, respectively), and stroke (29% of both cohorts).

In 2016, Blume et al published the first analysis of the Pediatric Interagency Registry for Mechanical Circulatory Support (PediMACS), which is a prospective, multicenter registry that collects data on patients who are under age 19 at the time of implant, and includes those
implanted with either durable or temporary VADs. At the time of analysis, the registry included 241 patients; of these, 41 were implanted with a temporary device only, leaving 200 patients implanted with VADs for the present study. Most patients (73%) had an underlying diagnosis of cardiomyopathy. At the time of implantation, 64% were listed for transplant, while 29% were implanted with a “bridge to candidacy” strategy. A total of 7% were implanted with a destination therapy strategy. Actuarial survival at both 6 months and 1 year was 81%. At 6 months, 58% of patients were transplanted.

Also in 2016, Wehman et al reported on posttransplant survival outcomes for pediatric patients who received a VAD, ECMO, or no mechanical circulatory support (MCS), in the pretransplant period. The study included 2777 pediatric patients who underwent heart transplant from 2005 to 2012 who were identified through the UNOS 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 posttransplant, 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<0.001). However, a model to predict time to death excluding deaths in the first 4 months posttransplant, the bridging group was not significantly associated with risk of death.

In 2013, Almond et al reported results from a prospective, multicenter registry to evaluate outcomes in children who received the Berlin Heart EXCOR device as a bridge to transplant. This study included a broader patient population than the Fraser study (discussed above). All patients were followed 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% who were alive with the device in place. In a follow-up study that evaluated 204 children from the same registry, Jordan et al 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.

In 2016, Chen et al reported on a retrospective, single-center series of pediatric patients with continuous-flow VADs, with a focus on outpatient experiences. The series included 17 children implanted with an intracorporeal device from 2010 to 2014. Eight (47%) patients were discharged after a median postimplant hospitalization duration of 49 days. Adverse events were common in outpatients, most frequently major device malfunction (31% [5/16] events) and cardiac arrhythmias (31% [5/16] events). At the time of analysis, 4 patients had received an orthotopic heart transplant, 2 were on ongoing support, and 1 each had been transferred or died.

Another retrospective, single-center series of pediatric patients reported on outcomes with short-term continuous-flow VADs, which including the Thoratec PediMag or CentriMag, or the Maquet RotaFlow. From 2015 to 2014, 27 children were supported with one of these devices, most commonly for congenital heart disease (42%). The median duration of support was 12 days, and 67% of all short-term continuous-flow VAD runs (19 of 28 runs) led to hospital discharge.
Section Summary: VADs as Bridge to Transplant
In adults, the evidence on the efficacy of VADs as bridge to transplant consists of numerous uncontrolled trials and trials comparing different VADs among patients with no other treatment options. In children, the evidence consists of several uncontrolled trials and 1 trial with historical controls. These studies reported that substantial numbers of patients survived to transplant in situations in which survival would not be otherwise expected. Despite the lack of high-quality controlled trials, this evidence is sufficient to determine that outcomes are improved in patients who have no other options for survival. The impact of pretransplant LVADs on survival from transplant is uncertain, with some studies reporting worse survival in patients receiving LVADs and other studies reporting similar or improved survival.

VADs as Destination Therapy
The evaluation of VADs as destination therapy is based on a 2002 TEC Assessment 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. 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 a VAD compared with treatment by optimal medical therapy. Median survival was improved by approximately 8.5 months. Serious adverse events were more common in the VAD group, but these appear to be outweighed by this group's better outcomes on function; New York Heart Association (NYHA) class was significantly improved, as was QOL among those living to 12 months.
- VAD 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.

Park et al published an extended 2-year follow-up of patients from the REMATCH trial, which found that survival and quality-of-life benefits were still apparent. In addition, this study and other case series suggested continuing improvement in outcomes related to ongoing improvements in the device and in patient management. However, the durability of the HeartMate device used in the REMATCH trial was a concern (eg, at 1 participating institution, all 6 long-term survivors required device change-outs).

After release of the REMATCH trial results, Rogers et al published results from a prospective, nonrandomized clinical trial comparing LVAD as destination therapy to optimal medical therapy for patients with heart failure who were not candidates for heart transplant. Fifty-five patients who had NYHA functional class IV symptoms and who failed weaning from inotropic support were offered a Novacor LVAD; 18 did not receive a device due to preference or device unavailability and acted as a control group. The LVAD-treated patients had superior survival rates at 6 months (46% vs 22%; p=0.03) and 12 months (27% vs 11%; p=0.02), along with fewer adverse events.

A subsequent prospective observational study comparing LVAD support (n=97) to 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. Twelve-month
survival was 80% in the LVAD group compared with 63% in the best medical therapy group (p=0.022).

In an FDA-required postapproval study of the HeartMate II device for destination therapy, which 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 of the original trial, which compared patients who received the HeartMate II to earlier generation devices (Slaughter et al [2009], described next). Survival in the postapproval cohort was 82% and 69% at 1 and 2 years postoperatively, respectively.

Section Summary: VADs as Destination Therapy
The main piece of evidence on the efficacy of LVADs as destination therapy in patients who are not transplant candidates is a multicenter RCT, the REMATCH trial. It reported that the use of LVADs led to improvements in survival, quality of life, and functional status. This evidence is sufficient to establish that health outcomes are improved with LVADs in this patient population.

Comparative Efficacy of Continuous-Flow Versus Pulsatile-Flow Devices
In December 2009, Slaughter et al published data from an unblinded randomized multicenter trial comparing a continuous-flow device with a pulsatile device. Subjects were randomly assigned to continuous-flow or pulsatile-flow devices on a 2:1 block-randomization basis. The primary outcome measured was a composite end point of 2-year survival, freedom from disabling stroke, or need for device replacement. Continuous-flow patients (n=134) reached the primary outcome at a rate of 46% (95% CI, 38% to 55%) compared with pulsatile-flow patients (n=66) at a rate of 11% (95% CI, 3% to 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 end point; 2-year death rate also favored this device (58% vs 24%, respectively; p=0.008). Stroke and death (within 2 years of implantation) were similar in the 2 groups (stroke rate, 12%; death rate, 36%). QOL 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 nonrandomized comparison of pulsatile- versus continuous-flow devices using data from the registry of the International Society for Heart and Lung Transplantation on 8557 patients undergoing transplant. Comparisons were made among patients receiving a pulsatile LVAD, a continuous-flow LVAD, and no LVAD. Two time periods were analyzed: pre-2004, when nearly all LVADs were pulsatile devices, and post-2004, when continuous use devices were introduced into clinical care. Comparing the 2 time periods, there was a significantly greater risk of mortality in the first than in the second (RR=1.30; 95% CI, 1.03 to 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 with the pulsatile group (RR=1.25; 95% CI, 1.03 to 1.65; p=0.03).

Dell’Aquila et al compared outcomes for patients treated with a third-generation continuous-flow device (HeartWare) to those for patients treated with older devices in a single-center study. Comparison group patients received either older continuous-flow or pulsatile-flow devices. Of 287 patients who received VAD support from 1993 to 2012, 52 received a HeartWare device, 76 an older continuous-flow device, and 159 an older pulsatile device. Survival was significantly better for patients who received a third-generation device, with 24 month survival of 70.4%, compared
with 33.7% for patients who received an older continuous-flow device and 33.8% for patients who received an older pulsatile-flow device (p=0.013). The difference in survival associated with third-generation devices was more pronounced for higher scores on the INTERMACs scale.

Other nonrandomized studies that have compared outcomes from different types of LVADs have been smaller and/or focused on physiologic outcomes.47-51 In some of these studies, the continuous-flow devices exhibit greater improvement in physiologic measures, but none reported significant differences in clinical outcomes between devices.

Section Summary: Comparative Efficacy of Continuous-Flow Versus Pulsatile-Flow Devices
The evidence on the comparative efficacy of different devices consists of 1 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 1 database study with large numbers of patients, have not reported important differences in clinical outcomes between devices.

Total Artificial Hearts
TAH as Bridge to Transplant
FDA approval of the CardioWest TAH was based on the results of a nonrandomized, prospective study of 81 patients.52 Patients had failed inotropic therapy, 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 with 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.53 All patients either met established criteria for mechanically assisted circulatory support or were failing medical therapy on multiple inotropic drugs. Mean support time was 87 days (range, 1-441 days). Survival to transplant was 68.3% (69/101). Of the 32 deaths before 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%.

TAH as Destination Therapy
Data on the artificial heart are available from FDA approval information54 and from a published article describing results for the first 7 patients.55 FDA indicated that its decision was based on the company's laboratory and animal testing and on a small clinical study of 14 patients conducted by Abiomed. The patients had a 1-month survival prognosis of not more than 30%, were ineligible for cardiac transplants, and were felt to not benefit from VAD therapy. The study showed that the device was safe and likely to benefit for people with severe heart failure whose death was imminent and for whom no alternative treatments were available. Of the 14 patients in the study, 12 survived surgery. Mean duration of support for the patients was 5.3 months. In some cases, the device extended survival by several months (survival was 17 months in 1 patient). Six patients were ambulatory; 1 patient was discharged home. Complications included postoperative bleeding and neurologic events. Device-related infection was "non-existent."
Longer Term Follow-Up
Torregrossa et al reported on 47 patients who received a TAH at 10 worldwide centers and had the device implanted for more than 1 year.\textsuperscript{56} 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 (72%) patients were successfully transplanted, 12 (24%) patients died while on device support, and 1 (2%) patient was still supported. Device failure occurred in 5 (10%) patients. Major complications were common, including systemic infection in 25 (53%) patients, driveline infections in 13 (27%) patients, thromboembolic events in 9 (19%) patients, and hemorrhagic events in 7 (14%) patients. Two of the deaths occurred secondary to device failure.

Section Summary: Total Artificial Hearts
There is a smaller amount of evidence on the use of TAH as a bridge to transplantation and as destination therapy compared with the use of LVADs. The type of evidence on bridge to transplant is similar to that for LVADs (ie, 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 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.

Percutaneous Ventricular Assist Devices
pVADs as an Alternative to Intra-Aortic Balloon Pump in Cardiogenic Shock
Romeo et al (2016) reported on a systematic review and meta-analysis that evaluated a variety of percutaneous mechanical support methods, including pVADs, for patients with cardiogenic shock due to AMI who were undergoing revascularization.\textsuperscript{57} This review included the 3 RCTs (described above) comparing pVADs with intra-aortic balloon pumps (IABPs), along with 3 observational studies. In the comparison of pVADs with IABP, the reviewers found that inhospital mortality (the primary outcome of the analysis) was not significantly increased in the pVAD group.

Three RCTs have compared pVADs with IABPs) for patients with cardiogenic shock,\textsuperscript{58-60} along with a 2009 meta-analysis of these 3 trials.\textsuperscript{61} The 3 RCTs enrolled a total of 100 patients, 53 treated with a pVAD and 47 treated with an IABP. All 3 trial populations included patients with AMI and cardiovascular shock; 1 trial restricted this population to patients who were postrevascularization in the acute MI setting. The primary outcomes reported were 30-day mortality, hemodynamic measures of left ventricle pump function, and adverse events.

All 3 trials reported an improvement in left ventricle hemodynamics in the pVAD group. On combined analysis, there was a mean increase in cardiac index of 0.35 L/min/m\(^2\) for the pVAD group, an increase in mean arterial pressure of 12.8 mm Hg (95% CI, 3.6 to 22.0 mm Hg; p<0.001), and a decrease in pulmonary capillary wedge pressure of 5.3 mm Hg (95% CI, 1.2 to 9.4 mm Hg; 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 to 3.93). Leg ischemia was also more common in the
pVAD group, but this difference was not statistically significant (RR=2.59; 95% CI, 0.75 to 8.97; p=0.13).

O’Neill et al compared outcomes for patients with AMI complicated by cardiogenic shock who received pVAD support pre-percutaneous coronary intervention (PCI) with those who received pVAD support post-PCI using data from 154 consecutive patients enrolled in a multicenter registry.62 Patients who received pVAD support pre-PCI had higher survival to discharge (65.1%) compared with those who received pVAD support post-PCI (40.7%; p=0.003). In multivariable analysis, receiving pVAD support pre-PCI was associated with in-hospital survival (odds ratio [OR], 0.37; 95% CI, 0.17 to 0.79; p=0.01).

Case series of patients treated with pVADs as an alternative to IABP in cardiogenic shock have been published and reported high success rates as a bridge to alternative therapies.63,64

pVADs as 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.65 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 L/min/m² to 3.0 L/min/m² (p<0.001), and systolic blood pressure increased from 75 mm Hg to 100 mm Hg (p<0.001). The authors concluded that pVAD rapidly reversed the terminal hemodynamic compromise noted in patients with severe refractory cardiogenic shock refractory to IABP and vasopressor support.

pVADs as Ancillary Support in High-Risk Patients Undergoing High-Risk Cardiac Procedures
In 2016, Briasoulis et al reported on a meta-analysis of pVAD devices as an adjunct to high-risk PCI.66 The reviewers included RCTs and cohort studies, identifying 18 nonrandomized observational studies and 1 RCT. The single RCT identified was the PROTECT II trial described in more detail below. In the observational studies, the sample sizes ranged from 7 to 637 patients. In pooled analysis, the 30-day mortality rate following Impella-assisted high-risk PCI was 3.5% (95% CI, 2.2% to 4.8%; I²=20%), while that for TandemHeart-assisted high-risk PCI was 8% (95% CI, 2.9% to 13.1%; I²=55%). The pooled vascular complication rates were 4.9% (95% CI, 2.3% to 7.6%) and 6.5% (95% CI, 3.2% to 9.9%) for the Impella and the TandemHeart, respectively.

The PROTECT trial evaluated whether the Impella 2.5 system improves outcomes for patients undergoing high-risk PCI procedures. 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 surgery.67 High-risk PCI was performed using the Impella system for circulatory support. All procedures were successfully completed without any hemodynamic compromise in-procedure. Two (10%) patient died within 30 days and 2 (10%) patients had a periprocedural MI. Two other 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 30 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 of the first 327 patients enrolled revealed that the primary end point could not be reached. When stopped, 452 patients had been enrolled, 3 of whom withdrew consent and 1 who died. Results were published by O’Neill et al in 2012.68 The study’s primary analysis was intention to treat and included all 448 patients randomly assigned to the Impella system (n=225) or IABP (n=223). The primary composite end point of major adverse effects at 30 days occurred in 35.1% of Impella patients and in 40.1% of the IABP patients (p=0.277). There was no significant difference in the occurrence of in-hospital death, stroke, or MI between the Impella patients and the IABP patients.

In a prespecified subgroup analysis of the PROTECT II trial, Kovacic et al compared outcomes for the Impella system and IABP among 325 patients with 3-vessel disease with a LVEF of less than or equal to 30%.69 In the 3-vessel disease subgroup, 167 subjects were randomized to PCI with Impella support and 158 to PCI with IABP support. PCI characteristics differed in that rotational atherectomy was more aggressively used in the Impella-support group, with more passes per patient (5.6 vs 2.8, p=0.002) and more passes per coronary lesion (3.4 vs 1.7, p=0.001). Acute procedural revascularization results did not differ between groups. At 30 days, the major adverse event rate did not differ significantly between groups (32.9% of Impella patients vs 42.4% of IABP patients, p=0.078). At 90 days, Impella patients (39.5%) had a significantly lower major adverse event rate compared with IABP patients (51.0%; p=0.039). The 90-day event rates for the individual components of the composite major adverse event score differed only for severe hypotension requiring treatment, which was more common in patients treated with IABP (7.6% vs 2.4%, p=0.029).

In a post hoc analysis, results of the PROTECT II trial were reanalyzed by Dangas et al, using a revised definition of MI in the determination of patients with major adverse events and major adverse cardiac and cerebral events.70 Unlike the original trial, which used a cutoff of 3 times the upper limit of normal for biomarker elevation to define periprocedural MI, the authors used a cutoff of 8 times the upper limit of normal for biomarker elevation or the presence of Q waves to define periprocedural MI. In multivariable analysis, compared with IABP, treatment with the Impella system was associated with freedom from 90-day major adverse events (OR=0.75; 95% CI, 0.61 to 0.92; p=0.007) and major adverse cardiac and cerebral events (OR=0.76; 95% CI, 0.61 to 0.96; p=0.020).

Other case series have described pVAD use in high-risk patients undergoing an invasive cardiac procedure. Sjauw et al retrospectively analyzed 144 consecutive patients undergoing high-risk PCI with pVAD support (Impella system) from a European registry.71 End points included successful device function and incidence of adverse events at 30 days. The device was successfully implanted in all 144 patients. There was 1 peri-procedural death and 8 deaths at 30 days for a mortality rate of 5.5%. Bleeding requiring transfusion or surgery occurred in 6.2% of patients, and vascular access site complications occurred in 4.0%. There was 1 (0.7%) stroke, and no MIs were reported. Maini et al performed a similar retrospective analysis of 175 patients undergoing high-risk PCI with pVAD support with the Impella 2.5 circulatory support system.72 The primary safety end point was the incidence of major adverse cardiac events at 30 days. Secondary end points included device safety and efficacy and patient outcomes at 30 days and 12 months. Angiographic revascularization was successful in 99% of patients. At 30-day follow-up, the major adverse cardiac event rate was 8%; survival was 96%, 91%, and 88% at 30 days,
6 months, and 12 months, respectively. Secondary safety end points occurring most frequently included acute renal dysfunction (2.8%), hypotension on support (3.4%), ventricular tachycardia (VT), or cardiopulmonary resuscitation (2.8%); other vascular complications included vessel dissection and arteriovenous fistula (3.4%), hematomas ipsi- or contralateral to the device insertion site (8.6%), infection (5.1%), and blood transfusion (9.7%).

Reddy et al reported outcomes for a series of 66 patients enrolled in a prospective, multicenter registry who underwent VT ablation with a pVAD or IABP.73 Twenty-two patients underwent ablation with IABP assistance, while 44 underwent ablation with either the TandemHeart or Impella pVAD device (non-IABP group). Compared with patients who received support with an IABP, those who received support with a pVAD had more unstable VTs that could be mapped and ablated (1.05 vs 0.32, p<0.001), more VTs that could be terminated by ablation (1.59 vs 0.91, p=0.001), and fewer VTs terminated with rescue shocks (1.9 vs 3.0, p=0.049). More pVAD-supported patients could undergo entrainment/activation mapping (82% vs 59%, p=0.046). Mortality and VT recurrence did not differ over the study follow-up period (average, 12 months).

In a retrospective study, Aryana et al reported procedural and clinical outcomes for 68 consecutive unstable patients with scar-mediated epicardial or endocardial VT who underwent ablation with or without pVAD support.74 Thirty-four patients had hemodynamic support periprocedurally with a pVAD. pVAD- and non-pVAD-supported patients were similar at baseline, with no differences in procedural success rates between groups. Compared with non-pVAD-supported patients, patients in the pVAD group had a longer maximum time in unstable VT (27.4 min vs 5.3 min, p<0.001), more VT ablations per procedure (1.2 vs 0.4, p<0.001), a shorter radiofrequency ablation time (53 seconds vs 68 seconds, p=0.022), and a shorter hospital length of stay (4.1 days vs 5.4 days, p=0.013). Over a follow-up period of 19 months, rates of VT recurrence did not differ between groups.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this policy are listed in Table 2.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT01187368</td>
<td>A Prospective Study to Evaluate the Safety and Efficacy of the EVAHEART LVAS for Use as a Bridge-to-Transplant</td>
<td>20</td>
<td>Dec 2016 (suspended)</td>
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<td>NCT01966458</td>
<td>A Prospective, Randomized, Controlled, Unblinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist Device System for Destination Therapy of Advanced Heart Failure</td>
<td>465</td>
<td>Oct 2016</td>
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<td>NCT01774656</td>
<td>Remission From Stage D Heart Failure (RESTAGE-HF)</td>
<td>40</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02387112</td>
<td>Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation</td>
<td>500</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT01369407</td>
<td>REVIVE-IT Registry (REVIVAL: Registry Evaluation of Vital Information for VADs in Ambulatory Life)</td>
<td>400</td>
<td>Jun 2019</td>
</tr>
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</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.
SUMMARY OF EVIDENCE
For individuals who have end-stage heart failure who receive a ventricular assist device (VAD) as bridge to transplant, the evidence includes single-arm clinical trials and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. There is a substantial body of evidence from clinical trials and observational studies supporting implantable VADs as a bridge to transplant in patients with end-stage heart failure, possibly improving mortality, as well as quality of life. 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes 1 clinical trial and multiple single-arm studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. A well-designed clinical trial, with 2 years of follow-up data, have demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for heart transplant. Despite an increase in adverse events, both mortality and quality of life appear to be improved for these patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a total artificial heart (TAH) as bridge to transplant, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, the lack of medical or surgical options for these patients and what 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 ventricular assist device. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock or who undergo a high-risk cardiac procedures who receive a percutaneous ventricular assist device (pVAD), the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Three RCTs of pVAD versus 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 fourth RCT comparing pVAD with IABP as an adjunct to high-risk percutaneous coronary interventions was terminated early due to futility; analysis of enrolled subjects did not demonstrate significant improvements in the pVAD group.

For individuals with cardiogenic shock refractory to IABP who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events,
functional outcomes, quality of life, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement.

**CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2014. Vetting focused on the use of percutaneous VADs in accordance with the American Heart Association/American College of Cardiology guidelines (2013) and the use of TAH as destination therapy. All providing input supported the use of implantable VADs as destination therapy subject to the guidelines in the policy statements. Most providing input considered TAHs to be investigational for destination therapy; reviewers noted that there are limited clinical trial data to support the use of TAHs as destination therapy.

Most of those providing input considered pVADs to be investigational as a “bridge to recovery” or “bridge to decision” and for all other indications. Some reviewers noted that pVADs may improve patients’ hemodynamics better than other alternatives, such as an IABP but are associated with more complications. Some reviewers noted that, despite a lack of evidence to indicate that pVADs improve overall outcomes, there may be cases when pVADs may be considered to support an intervention or treatment for a life-threatening condition.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**Society for Cardiovascular Angiography and Interventions et al**

In 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America (HFSA), the Society of Thoracic Surgeons, and the American College of Cardiology published a clinical expert consensus statement on the use of percutaneous mechanical circulatory support (MCS) devices in cardiovascular care. This statement addressed IABPs, left atrial-to-aorta assist device (eg, TandemHeart), left ventricle-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 and American Heart Association**

The American College of Cardiology Foundation and American Heart Association (ACCF/AHA) released guidelines for the management of heart failure in October 2013 that include recommendations related to the use of for mechanical circulatory support (MCS), including both durable and nondurable MCS devices. The guidelines categorize pVADs and extracorporeal VADs as nondurable MCS devices. The following class IIa guidelines are made related to MCS devices:

- MCS is beneficial in carefully selected patients with stage D heart failure with reduced ejection fraction (HFrEF) in whom definitive management (eg, cardiac transplantation) or cardiac recovery is anticipated or planned. (Level of Evidence: B)
• Nondurable MCS, including the use of percutaneous and extracorporeal VADs, is reasonable as a “bridge to recovery” or “bridge to decision” for carefully selected patients with HF/EF with acute, profound hemodynamic compromise. (Level of Evidence: B)

• Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HF/EF. (Level of Evidence: B)

The ACCF/AHA guidelines note:

“Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with LVEF <25% and NYHA [New York Heart Association] class III-IV functional status despite GDMT [guideline-directed medical therapy], including, when indicated, CRT [cardiac resynchronization therapy], with either high predicted 1- to 2-year mortality (eg, as suggested by markedly reduced peak oxygen consumption and clinical prognostic scores) or dependence on continuous parenteral inotropic support. Patient selection requires a multidisciplinary team of experienced advanced HF [heart failure] and transplantation cardiologists, cardiothoracic surgeons, nurses, and ideally, social workers and palliative care clinicians.”

In 2012, AHA published recommendations for the use of MCS. These guidelines define nondurable MCS as intraballon pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. The following recommendations were made regarding indications for use of MCS, including durable and nondurable devices:

• MCS for bridge-to-transplant indication should be considered for transplant-eligible patients with end-stage heart failure who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation. (Class I; Level of Evidence B).

• Implantation of MCS in patients before the development of advanced heart failure is associated with better outcomes. Therefore, early referral of heart failure patients is reasonable. (Class IIa; Level of Evidence B).

• MCS with a durable, implantable device for permanent therapy or destination therapy is beneficial for patients with advanced heart failure, high 1-year mortality resulting from heart failure, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation. (Class I; Level of Evidence B).

• Elective rather than urgent implantation of destination therapy can be beneficial when performed after optimization of medical therapy in advanced heart failure patients who are failing medical, surgical, and/or device therapies. (Class IIa; Level of Evidence C).

• Urgent nondurable MCS is reasonable in hemodynamically compromised heart failure patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile. (Class IIa; Level of Evidence C).

• These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced heart failure. (Class I; Level of Evidence C).

• Patients who are ineligible for heart transplantation because of pulmonary hypertension related to heart failure alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS. (Class IIa; Level of Evidence B).
Heart Failure Society of America
The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. The following recommendations were made regarding LVADs:

- 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)
- Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF [heart failure] 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)
- 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)

European Society of Cardiology
In 2012, the European Society of Cardiology issued guidelines for the diagnosis and treatment of acute and chronic heart failure, which were an update to previous guidelines published in 2008 and 2010. These guidelines make the following recommendation regarding VADs:

- An LVAD or BiVAD is recommended in selected patients with end-stage heart failure despite optimal pharmacological and device treatment and who are otherwise suitable for heart transplant, to reduce the risk of heart failure hospitalization for worsening heart failure and to reduce the risk of premature death while awaiting transplant. (Class I, Level B recommendation).
- An LVAD should be considered in highly selected patients with end-stage heart failure despite optimal pharmacological and device therapy and who are not suitable for heart transplant, but are expected to survive greater than 1 year with good functional status, to improve symptoms and to reduce the risk of heart failure hospitalization and of premature death. (Class IIa, Level B recommendation).

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

CODING
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

CPT/HCPCS

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<tr>
<th>Code</th>
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<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
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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 ventricle
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

ICD-10 Diagnoses (Effective October 1, 2015)
I09.81   Rheumatic heart failure
I11.0    Hypertensive heart disease with heart failure
I13.0    Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2    Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I15.1    Left ventricular failure
I15.20   Unspecified systolic (congestive) heart failure
I15.21   Acute systolic (congestive) heart failure
I15.22   Chronic systolic (congestive) heart failure
I15.23   Acute on chronic systolic (congestive) heart failure
I15.30   Unspecified diastolic (congestive) heart failure
I15.31   Acute diastolic (congestive) heart failure
I15.32   Chronic diastolic (congestive) heart failure
I15.33   Acute on chronic diastolic (congestive) heart failure
I15.40   Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I15.41   Acute combined systolic (congestive) and diastolic (congestive) heart failure
I15.42   Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I15.43   Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I197.0   Postcardiotomy syndrome

REVISIONS
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<tr>
<td>10-01-2016</td>
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<tr>
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<td>Updated Rationale section.</td>
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<td>Updated References section.</td>
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</table>
Title revised from "Total Artificial Hearts and Implantable Ventricular Assist Devices".

In Policy section:
- Added new Item D, "Percutaneous ventricular assist devices are intended for partial circulatory support for a limited period of time. The use of an FDA-approved percutaneous ventricular assist device may be considered medically necessary for short-term stabilization of patients with ANY of the following indications: 1. Cardiogenic shock that is refractory to medications and intra-aortic balloon pump (IABP); OR 2. Cardiogenic shock, as an alternative to IABP; OR 3. High-risk patients undergoing invasive cardiac / electrophysiological procedures who need circulatory support.
- In Item E, add "other" to read, "Percutaneous ventricular assist devices are considered experimental / investigational for all other indications."
- Previous Item D is now Item F.

Updated Rationale section.
Updated References section.

REFERENCES


37. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.


68. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk


79. McMurray JJ, Adamopoulos S, Anker SD, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur Heart J. Jul 2012;33(14):1787-1847. PMID 22611136


Other References
2. Blue Cross and Blue Shield of Kansas Cardiology Liaison Committee Consent Ballot, February 2017.