Ventricular Assist Devices and Total Artificial Hearts

Effective: March 1, 2025

Next Review: December 2025
Last Review: January 2025

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

Note: This 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; and
         b. Not expected to survive until a donor heart can be obtained; or

2. For use in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass; or
3. As destination therapy in patients meeting all of the following criteria (a.- e.):
    a. End-stage heart failure; and
    b. New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV (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.); and
    c. Left ventricular ejection fraction 25% or less; and
    d. One of the following criteria is met:
        i. Inotrope-dependent; or
        ii. Cardiac index is less than 2.2 liters per minute per meter squared while not on inotropes; and
    e. One of the following criteria is met:
        i. On optimal medical management, including beta-blockers and/or ACE inhibitors if not contraindicated, for at least 45 of the last 60 days and are failing to respond; or
        ii. Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for 7 days or more.

B. Ventricular assist devices and aortic counterpulsation devices are considered **investigational** in all other circumstances, including but not limited to the 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; and
2. Currently listed as heart transplantation candidate or undergoing evaluation to determine candidacy for heart transplantation; and
3. Not considered a candidate for a univentricular or biventricular support device; and
4. Have no other reasonable medical or surgical treatment options; and
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; or
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.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- For Implantable Ventricular Assist Devices:
  - Documentation as to whether this is a bridge to heart transplant, being used post-cardiotomy for patient who is unable to be weaned of cardiopulmonary bypass, or as destination therapy
  - For destination therapy:
    - Documentation of end-stage heart failure, documentation of ejection fraction, documentation of inotrope dependency or cardiac index score when not on inotropes, documentation of optimal medical management or documentation of advanced heart failure and dependency on an intra-aortic balloon pump, and current NYHA classification, including duration of NYHA classification, symptoms, and treatments tried.
- For Total Artificial Heart:
  - Documentation that this is a bridge to heart transplant and patient has biventricular failure; is listed as heart transplant candidate or undergoing evaluation to determine candidacy for heart transplant; is not considered a candidate for univentricular or biventricular support device; has no other reasonable medical or surgical treatment options; and is not expected to survive until a donor heart can be obtained

CROSS REFERENCES

1. Extracorporeal Membrane Oxygenation (ECMO) for the Treatment of Cardiac and Respiratory Failure in Adults, Medicine, Policy No. 152
2. Surgical Ventricular Restoration, Surgery, Policy No. 149
3. Heart Transplant, Transplant, Policy No. 02
4. 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 (RVADs), 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
HeartMate 3™	LVAD	Thoratec Corp.	PMA	Bridge to transplant and destination therapy
Thoratec® IVAD	BiVAD	Thoratec Corp.	PMA + Supplement	Bridge to transplant and postcardiotomy
Centrimag®	RVAD	Thoratec Corp.	PMA	Postcardiotomy, bridge to decision
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)

Device Name	Device Type	Manufacturer	FDA Approval	Indication
Jarvik 2000	LVAD	Jarvik Heart, Inc.	*IDE-Investigational*†	
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.[1]

In August 2016, HeartWare® recalled its VAD Pumps due to a design flaw that was deemed by FDA as potentially causing serious injuries or death (class I recall). The devices affected were manufactured and distributed from March 2006 and May 2018. The device was discontinued in 2021 due to evidence demonstrating a higher frequency of neurological adverse events and mortality compared to other devices. FDA product codes: 204 and 017. Additional FDA class I and II recalls associated with the HeartWare VAD have been issued in since the HeartWare® was discontinued in 2021.[2]

A class I recall was issued for the HeartMate 3™ in April 2018 affecting all manufacturing dates. FDA product code: DSQ.

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 (SR) published in 2011 supported the conclusions reached in the 1996 BCBSA TEC assessment.[3, 4] 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 to 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 to 1.22). There was no difference in the risk of rejection between patients who did and did not receive LVAD treatment.

Nonrandomized Studies

Adult PatientsAdditional reports not included in the 1996 TEC assessment or the 2011 SR are consistent with the above analysis.[5-7] 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.[8-13]

Pagani (2021) used Medicare claims data to analyze survival outcomes in patients who received different LVADs between January 2014 and December 2018, with followup through December 2019.[14] Of 4195 patients who received implants, there were 117 (14.3%) deaths among 821 Heartmate3™ patients, 375 (20.4%) deaths among 1840 Heartmate II® patients, and 375 (24.5%) deaths among 1534 patients with other VADs. The adjusted hazard ratio for mortality at 1-year (confirmed in a propensity score matched analysis) for the HeartMate 3 versus HeartMate II® was 0.64 (95% CI; 0.52 to 0.79, p<.0001) and for the HeartMate 3™ versus other-VADs was 0.51 (95% CI; 0.42 to 0.63, p<.0001).

Aissaoui (2018) published an observational study comparing 224 patients in Germany and France with end-stage heart failure who received VAD as first option (group I, n=83) or either heart transplantation or medical therapy as first option (group II, n=141).[15] The estimated two-year survival was 44% for group I and 70% for group II (p<0.001). The study was limited by the lack of randomization and possible patient selection bias.

Grimm (2016) compared outcomes for patients based on the duration of LVAD use, using data from the United Network for Organ Sharing database.[16] 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 to 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, six-month survival, or one-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 (2016),which used the United Network for Organ Sharing database, suggested that patients bridged to transplant with an LVAD have better outcomes than those bridged with TAH or biventricular assist devices.[17] Cheng (2016) compared BiVAD to TAH outcomes in this database, and found similar wait-list survival between the groups.[18]

Deo (2014) 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.[19] In 2013, Slaughter reported combined outcomes for patients included in the HeartWare® bridge-to-transplant study.[20] 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.

Aaronson (2012) 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.[21] 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.[22-27] Survival rates at six months and one year were 67% to 87%, and 50% to 80%, respectively. These rates are similar to those reported from INTERMACS.[28] 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.[29] 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.[24] 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.[30]

Pediatric Patients

Systematic Review

Palazzolo (2022) published a SR to analyze current landscape of pediatric mechanical circulatory assist (MCA) devices.[31] They included 27 devices including VADs, Fontan assist devices and TAHs. The authors conclude that there is still not sufficient pump technology that meets the constraints of a pediatric population such as patient sizes, increased cardiovascular demand with growth and physiologic heterogeneity of congenital heart disease.

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.[32] Davies (2008) reported that pediatric patients requiring a pretransplantation VAD had similar long-term survival to those not receiving mechanical circulatory support.[33]

A retrospective registry study by Jeewa (2018) assessed long-term outcomes for pediatric VAD use as a bridge to transplantation in patients from the Berlin Heart investigational device exemption trial.[34] These patients (n=109) were compared with matched controls from the Pediatric Heart Transplant Study who did not require mechanical circulatory support (n=166). There was no significant difference between the groups for five-year survival (81% for VAD, 88% for non-VAD, p=0.09) or for rates of infection or rejection.

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).[35] 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).

Almond (2013) reported results from a prospective, multicenter registry to evaluate outcomes in children who received the Berlin Heart EXCOR® device as a bridge to transplant.[36] 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.[37] 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.[38]

Wehman (2016) reported on post-transplant survival outcomes for pediatric patients who received a VAD, extracorporeal membrane oxygenation (ECMO), or no mechanical circulatory support, in the pre-transplant period.[39] The study included 2,777 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 five-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 four 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 four 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

VADs may have a role in bridging patients to recovery, particularly if there is reverse remodeling of the left ventricle. Several additional studies have investigated the role of VADs in bridging patients to decision.

Systematic Reviews

Reid (2022) published an SR with meta analysis to evaluate the outcomes for patients undergoing right ventricular assist device (RVAD) implantation following left ventricular assist device (LVAD) implantation.[40] A total of 35 studies were included (3260 patients). The primary endpoint was mortality during the hospital stay and at follow-up. Mortality reported at short-term as well at long-term was 19.66% (CI 15.73-23.59%) and 33.90% (CI 8.84-59.96%) in LVAD respectively versus 45.35% (CI 35.31-55.4%) $p \leqslant 0.001$ and 48.23% (CI 16.01-80.45%) $p = 0.686$ in LVAD/RVAD group respectively. The authors conclude temporary RVAD implantation following LVAD is associated with decreased in-hospital, as well as short-term survival as compared to isolated LVAD implantation. The analysis is limited due to incomplete reporting, small sample sizes, and that the LVAD/RVAD cohorts are likely to be sicker and therefore have a higher mortality.

A scoping review with meta-analysis of selected studies was completed to examine the impact of 3rd generation LVADs on quality of life.[41] Eleven articles met the inclusion criteria. Three were randomized trials and eight were retrospective and registry studies. A meta-analysis was completed on four studies which included the EroQOL 5L tool at 6 months post LVAD implantation and reported a mean difference increase of 28.9 points (95% CI: 26.71 – 31.41). The authors conclude that the improved QOL support use of LVAD not only for prognosis but also for symptom control. The data are limited by lack of randomized studies and limited number of studies included in the meta-analysis.

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.[7, 42, 43]

Agrawal (2018) published a retrospective cohort study evaluating the 30-day readmissions of 2,510 patients undergoing LVAD implantation.[44] Of the patients who met the inclusion criteria, 788 (31%) were readmitted within 30 days after surviving initial index hospitalization. Cardiac causes accounted for 23.8% of readmissions, 13.4% due to heart failure, and 8.1% to arrhythmias. Infection (30.2%), bleeding (17.6%), and device-related causes (8.2%) comprised the 76.2% of non-cardiovascular causes for readmission. The study's limitations relate to the nature of nonclinical data collection and gaps in current subject knowledge.

A retrospective cohort study by Adesyiun (2017) assessed LVAD complications and overall effect on mortality to determine factors associated with development of early and long-term complications.[45] Utilizing logistic regression and Cox proportional hazards analyses at univariable and multivariable stages, the study found 24% of patients developed early complications and 18.5% developed both early and late complications. There was a significant association between death and early complications (p=0.017), while the additional presence of two or more complications produced a 2.7-fold increase in mortality odds (p=0.016). Mortality odds increased by 20% with each subsequent complication (p=0.004). The study was limited in that, during its long, 13-year team span, practice associated with LVAD maintained had changed but were not address by the study. Further limitations include the difficulty in determining the strictness to which a patient might have met the complication definitions, as well as the small sample size of the study.

Kawajiri (2017) evaluated the outcomes of patients with end-stage heart failure who had conventional surgery as opposed to transplant or mechanical support.[46] A total of 133 patients of this retrospective cohort study were identified with left ventricular ejection fraction (LVEF) less than 20% and VO2 max < 14 mL/min/m^2 and, after initial referral for advanced therapies, were instead offered a conventional procedure. Of the originally identified 133 patients, 68 were determined transplant eligible. Actuarial survival at 5 and 10 years was 72% and 39%, respectively, after 12% in-hospital mortality. Outcomes were acceptable for conventional cardiac surgery in highly selected patients with end-stage HF, and long-term survival was comparable with advanced surgical therapies. The study was limited by a small study population, its nonclinical nature, and the potential underestimation the VAD/transplant mortality by measuring survival dates starting from first surgery as opposed to date of decision.

Raju (2017) focused their retrospective cohort study on consecutive LVAD patients who received more than one year of total LVAD support time.[47] During the study period, 103 patients received LVADs, 37 received LVAD support for more than one year, and 18 received support for more than two years. Average support time was 786 days. Mortality and hospital readmissions were used to determine the efficacy of continuous-flow LVADs. During a median follow-up of two years, the one-year conditional survival was 74%. Readmission reasons were due to major infection (24%), major bleeding (19%), and device malfunction/thrombosis (13%), and totaled 112 completed readmission procedures, 60% of which were done in 13% (n=5) of patients. The study had the limitations of a descriptive retrospective analysis and small sample size, and quality of life (QOL) self-assessments would have provided necessary patient perspective.

Takayama (2014) 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.[48] 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 to 26 days), 30% of patients had myocardial recovery, 15% had device exchange to an implantable VAD, and 18% had a heart transplantation.

Acharya (2016) 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.[49] 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=9,727). 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 one-month post VAD, 91.8% of the AMI group were alive with the device in place. At one-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%, $p<0.0001$).[50]

Topkara (2016) reported a similar analysis of 13,454 INTERMACS adults with implants between June 2006 and June 2015 without TAH, pulsatile-flow LVAD, or heart transplant.[51] Device explant rates for cardiac recovery were 0.9% at one-year, 1.9% at two-year, and 3.1% at three-year follow-up. An additional 9% of patients demonstrated partial cardiac recovery.

In a smaller single-center retrospective cohort study, Mohamedali (2015) 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.[52] 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.[43, 53-57] 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 (2007) evaluated 67 patients with heart failure who had undergone LVAD implantation for severe heart failure.[58] After 30 days, patients demonstrated significant improvements compared with pre-LVAD state in 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.[59] Eleven of 15 patients had enough myocardial recovery to undergo LVAD explantation; two patients died after explantation. Among those who survived, the cumulate 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 cardiopathy who had nonpulsatile LVADs implanted.[60] They included 20 patients who received a combination of angiotensin converting enzyme ACE inhibitors, beta blockers, and adosterol 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 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. 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[61] 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.[62] 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.

Systematic Reviews

Hanafy (2024) published a systematic review and meta-analysis to aid in clinical decision-making for exchanging older ventricular assist device models HeartMate 2™ (HM2) with the newest one, HeartMate 3™ (HM3).[63] The review included 49 studies with 31,105 patients. HM3 is the best device exchange choice that causes the lowest risk of mortality (HM3 (99.98) > HM2 (32.43) > HVAD (17.58)), cerebrovascular accidents (HM3 (99.99) > HM2 (42.41) > HVAD (7.60)), other neurologic events beside cerebrovascular accident (HM3 (91.45) > HM2 (54.16) > HVAD (4.39)), pump thrombosis (HM3 (100.00) > HM2 (39.20) > HVAD (10.80)), and bleeding (HM3 (97.12) > HM2 (47.60) > HVAD (5.28)). HM3 is also better than HM2 in hospital admissions (OR: 1.90 (95% CI: 1.15-3.12)). When complications were present, HM2 or Heartware ventricular assist devices exchange to HM3 lowered the mortality rate compared to exchanging it to the same device type.

Randomized Controlled Trials

The MOMENTUM 3 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 transplant or destination therapy; inclusion criteria included 1) NYHA Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV; 1) left ventricular ejection fraction ≤ 25%; 3) inotrope-dependent OR cardiac index <2.2 liters/min/m2 while not on inotropes plus on optimal medical management for at least 45 of the last 60 days and failing to respond or with advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days.[64, 65] HeartMate 3 ™ received PMA approval as a bridge to transplant therapy in August 2017 and as destination therapy in October 2018. The destination therapy indication was based on 2-year results from MOMENTUM 3, which showed superiority of the HeartMate 3 device compared to HeartMate II on the composite primary outcome, survival at two years free of disabling stroke or reoperation to replace a malfunctioning device (relative risk 0.84; 95% CI, 0.78–0.91, p<.001). Prevalence of stroke at 2 years was lower in the HeartMate 3 than the HeartMate 2® group (10.1% vs 19.2%; p=.02). Measures of functional capacity and Health-Related QOL did not differ between the two devices at six months.

A prespecified subgroup analysis of MOMENTUM 3 published in 2020 did not find differences in outcomes based on preoperative categories of bridge to transplant, bridge to transplant candidacy, or destination therapy.[66] Additionally, nearly 15% of those initially deemed transplant ineligible were eventually transplanted within 2 years of follow-up, supporting that clinical categorizations based on transplant eligibility should no longer be used. Park (2005) 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.[67]

Slaughter (2009) published data from an unblinded randomized multicenter trial.[68] 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 two-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% CI 38 to 55) compared to pulsatile-flow patients (n=66) 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 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

Jorde (2014) published results from an FDA-required postapproval study of the HeartMate II® device for destination therapy.[69] 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).[68] 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.[70] 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.[71] 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.

The evidence on the comparative efficacy of continuous-flow vs pulsatile-flow devices consists of an 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.[68] Other nonrandomized comparative studies, including a database study with large numbers of patients, have not reported important differences in clinical outcomes between devices.

CONTINUOUS-FLOW VS PULSATILE-FLOW DEVICES

Nonrandomized Studies

Mehra (2022) published a five year observational follow-up study in patients with Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial.[72] A total of 477 patients (295 enrolled between June 2019 and April 2021 and 182 provided limited data) of 536 patients still receiving LVAD support at 2 years contributed to the extended-phase analysis (median age, 62 y; 86 [18%] women). The 5-year Kaplan-Meier estimate of survival to transplant, recovery, or LVAD support free of debilitating stroke or reoperation to replace the pump in the centrifugal-flow vs axial-flow group was 54.0% vs 29.7% (hazard ratio, 0.55 [95% CI, 0.45-0.67]; P < .001). Overall Kaplan-Meier survival was 58.4% in the centrifugal-flow group vs 43.7% in the axial-flow group (hazard ratio, 0.72 [95% CI, 0.58-0.89]; P = .003). Serious adverse events of stroke, bleeding, and pump thrombosis were less frequent in the centrifugal-flow pump group. The authors conclude that these findings support the use of the fully magnetically levitated LVAD.

A post-pivotal trial continuous access protocol was initiated as a single-arm prospective study to assess the reproducibility of HeartMate3™ LVAD outcomes across centers used in the MOMENTUM 3 trail.[73] A total of 515 patients were included in the pivotal cohort. The primary outcomes for this extended study were survival to transplant, recovery, or ongoing LVAD support, free of disabling stroke or reoperation to replace or remove a malfunctioning pump, at 2 years post-implant. At 2 years post-implant, a similar proportion of patients in the continuous access group versus the pivotal cohort achieved the composite endpoint (76.7% vs 74.8%; adjusted HR, 0.87; 95% CI, 0.71 to 1.08; p=.21). Pump exchange rates were low in both cohorts with 98.4% of the continuous access cohort and 96.9% of the pivotal cohort being free of pump replacement at 2 years. Overall survival at 2 years was 81.2% in the continuous access cohort compared to 79% in the pivotal cohort. After controlling for baseline demographics between cohorts, the adjusted HR for continuous access versus pivotal cohort was 0.84 (95% CI, 0.67 to 1.06; p=.15). Survival based on if the HeartMate3™ was used as a bridge to transplant or as destination therapy was similar between the continuous access and pivotal trial cohorts (bridge to transplant adjusted HR, 0.70; 95% CI, 0.43 to 1.14; p=.15; destination therapy adjusted HR, 0.89; 95% CI, 0.68 to 1.16; p=.38). This additional trial in a larger cohort reproduced similar results to the initial MOMENTUM 3 study, especially in individuals using VADs as destination therapy.

Dell'Aquila (2014) 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.[74] 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 INTERMACs scale.

Nativi (2011) 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 8,557 patients undergoing transplant.[75] 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. There was a significantly greater risk of mortality in the first time period compared to the second time period (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 to the pulsatile group (RR 1.25, 95% CI 1.03 to 1.65, p=0.03).

Other nonrandomized studies that have compared outcomes from different types of LVADs have been smaller and/or focused on physiologic outcomes.[76-79] 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™ has been recalled. 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.[80] 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.[81] 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 to 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 four 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 (2014) reported on 47 patients who received a TAH at 10 worldwide centers and had the device implanted for more than one year.[82] 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 (2004) reported on the first seven patients in the AbioCor® clinical trial.[83] 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 (2004) reported information on four additional patients receiving the AbioCor®.[84] 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.[85] 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 ASSOCIATION FOR THORACIC SURGERY/INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION[86]

In 2020, the American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation published guidelines on selected topics in mechanical circulatory support. The guidelines noted that “Compared with IABP, contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar.” The level of evidence was graded at B and class of evidence was graded IIA.

AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION / AMERICAN HEART ASSOCIATION / HEART FAILURE SOCIETY OF AMERICA (ACCF/AHA/HFSA)[87]

The 2013 ACCF/AHA practice guidelines for the management of heart failure included the recommendations below related to 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 one- to two-year mortality or dependence on continuous parenteral inotropic support.

In 2017, the ACCF/AHA/HFSA published a focused update of the 2013 recommendations released by the ACCF and AHA.[88] LVAD was one of several treatment options recommended for patients with refractory NYHA class III or IV heart failure (stage D). If symptoms were not improved after guideline-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then LVAD was presented as an additional treatment option. The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged.

The AHA/ACC/HFSA published updated guidelines in 2022 to consolidate the 2013 and 2017 guidelines and to provide contemporary evidence.[89] The use of LVADs in patients with stage D HF is an included focus. The guidelines provide the highest class of recommendation (COR =1) and strongest level of evidence (LOE = A) that In select patients with advanced HFrEF with NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, QOL, and survival. (Class or Recommendation (COR) level 1 and Level of Evidence (LOE) = A. Additionally, In select patients with advanced HFrEF who have NYHA class IV symptoms despite GDMT, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality (COR II A; LOE B-R). Where COR A is high quality evidence from more than 1 RCT; B-R: Moderate-quality evidence from 1 or more RCTs; B-NR: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. The updated guidelines are silent on the use of artificial hearts.

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.[80] 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 transseptal 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
	33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
	33980	Removal of ventricular assist device, implantable intracorporeal, single ventricular
	33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
	33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
	33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
	33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only
	33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
	33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
	33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
	33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
	33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion
	33999	Unlisted procedure, cardiac surgery
HCPCS	L8698	Miscellaneous component, supply or accessory for use with total artificial heart system
	Q0477 – Q0509	Ventricular assist device accessories, code range

Date of Origin: *January 1996*