



BlueCross BlueShield
of Alabama

Name of Policy:

Ventricular Assist Devices and Total Artificial Hearts

Policy #: 033
Category: Surgery

Latest Review Date: February 2014
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Mechanical devices to assist or replace a failing heart have been developed over many decades of research. 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.

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.

Initial research into mechanical assistance for the heart focused on the total artificial heart, 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 utilize 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 heart must be removed, failure of the device is synonymous with cardiac death.

Left Ventricular Assist Devices (LVAD)

Implantable ventricular assist devices 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. Ventricular assist devices 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 utilize a pump which provides continuous flow. Continuous devices may move blood in rotary or axial flow.

Surgically-implanted ventricular assist devices 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. They 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 cardiectomy affecting the ventricular wall may preclude VAD use.

Devices in which the majority of the system's components are external to the body are for short-term use (six 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, i.e., are not implanted. These may be referred to as percutaneous VADs.

Percutaneous ventricular assist devices (pVAD)

pVADs have been developed for short-term use in patients who require acute circulatory support. These devices are placed through the femoral artery. Two different pVADs have been developed, the TandemHeart™ (Cardiac Assist™, Pittsburgh, PA), and the Impella® device (AbioMed™, Aachen, Germany). In the TandemHeart™ system, a catheter is introduced through the femoral artery and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral ~~artery~~ vein. The Impella device is also introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter that is placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction (MI), stroke, and arrhythmias.

There are several situations in which pVAD 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.

Policy:

Effective for dates of service on or after February 22, 2012:

Total artificial hearts with FDA-approved devices meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when performed in a Medicare-approved heart transplant facility as a bridge to heart transplantation and patients must:

- have biventricular failure **AND**,
 - have no other reasonable medical or surgical treatment options **AND**,
 - be ineligible for other univentricular or biventricular support devices **AND**,
 - be currently listed as heart transplantation candidates
- OR
- are undergoing evaluation to determine candidacy for heart transplantation **AND**,
 - not be expected to survive until a donor heart can be obtained.

Ventricular assist device (VAD) implantation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage only when performed in a Medicare-approved heart transplant facility **OR** Medicare-approved VAD destination therapy facility **AND** follows individual criteria for specific indications listed below. A list of these facilities is maintained on the CMS web site and available at

www.cms.gov/CertificationandCompliance/Downloads/ApprovedTransplantPrograms.pdf

and

Bridge to Transplantation

Adult

Ventricular assist devices that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage if the following criteria are met:

- Patients diagnosed with severe congestive heart failure (CHF) and used as a **bridge to transplantation** who meet the criteria listed below:
 - Approved heart transplant candidate by an approved heart transplant center;

OR

A patient who is undergoing evaluation to determine candidacy for heart transplantation.
 - At risk of dying before a donor heart is available.
 - The criteria listed below may be used as hemodynamic selection criteria:
 - Either a left atrial pressure of 20m Hg or a cardiac index of less than 2.0L/min/m while on maximum medical support;
 - Patients who are usually being treated as inpatients and according to the American Heart Association or comparable, as Class IV CHF;
 - Classified as status I by the United Network for Organ Sharing (considered the highest priority for transplantation).
 - On optimal inotropic (influencing the contractility of muscular tissue) support.
 - If possible, on an intra-aortic balloon pump.

Pediatric

Ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **children 16 years old and younger** as a **bridge to heart transplantation** 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 transplant.

Bridge to Recovery

Ventricular assist devices that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **patients in the post-cardiotomy setting who are unable to be weaned off cardiopulmonary bypass**.

Percutaneous ventricular assist devices (pVAD) that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for use in patients undergoing high risk percutaneous coronary intervention (PCI) when **ALL** of the following are met:

- Patient has LVEF of less than 35% **and**;
- Will undergo PCI on an unprotected left main coronary artery or last patent coronary conduit.

Destination Therapy

FDA approved ventricular assist devices when used as a permanent alternative (**destination therapy**) for patients with chronic end-stage heart failure and who are not candidates for heart transplantation **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage when **ALL** of the following conditions are met:

- New York Heart Association (NYHA) Class IV heart failure not responding to optimal medical management for at least 60 days, or NYHA Class III/IV for at least 28 days, received ≥ 14 days support with an intra-aortic balloon pump or dependent on intravenous (IV) inotropic agents, with 2 failed weaning attempts; **AND**
- Left ventricular ejection fraction (LVEF) $< 25\%$; **AND**

In addition, patients must not be candidates for human heart transplant for one or more of the following reasons:

- Age > 65 years; **or**
- Insulin-dependent diabetes mellitus with end-organ damage; **or**
- Chronic renal failure with serum creatinine > 2.5 mg/dl for ≥ 90 days; **or**
- Other clinically significant condition.

Other Indications

Ventricular assist devices for conditions other than those listed above do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Use of a non-FDA approved ventricular assist device does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and Technology Evaluation Criteria (TEC) and is considered **investigational**.

Effective for dates of service prior to February 22, 2012:

Ventricular assist device (VAD) implantation meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage only when performed in a Medicare-approved heart transplant facility **AND** follows individual criteria for specific indications listed below. A list of these facilities is maintained on the CMS web site and available at www.cms.hhs.gov/MedicareApprovedFacilite/VAD/list.asp#TopOfPage

Bridge to Transplantation

Adult

Ventricular assist devices that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage if the following criteria are met:

- Patients diagnosed with severe congestive heart failure (CHF) and used as a **bridge to transplantation** who meet the criteria listed below:
 - Approved heart transplant candidate by an approved heart transplant center.
 - At risk of dying before a donor heart is available.
 - The criteria listed below may be used as hemodynamic selection criteria:
 - Either a left atrial pressure of 20m Hg or a cardiac index of less than 2.0L/min/m while on maximum medical support.

- Patients who are usually being treated as inpatients and according to the American Heart Association or comparable, as Class IV CHF.
- Classified as status I by the United Network for Organ Sharing (considered the highest priority for transplantation).
- On optimal inotropic (influencing the contractility of muscular tissue) support.
- If possible, on an intra-aortic balloon pump

Pediatric

Ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **children aged 5 to 16** as a **bridge to heart transplantation** 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 transplant.

Total artificial hearts do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Bridge to Recovery

Ventricular assist devices that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in **patients in the post-cardiotomy setting who are unable to be weaned off cardiopulmonary bypass**.

Effective for dates of service on or after June 25, 2009:

Percutaneous ventricular assist devices (pVAD) that have FDA approval or clearance **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for use in patients undergoing high risk percutaneous coronary intervention (PCI) when **ALL** of the following are met:

- Patient has LVEF of less than 35% **and**;
- Will undergo PCI on an unprotected left main coronary artery or last patent coronary conduit.

Destination Therapy

FDA approved ventricular assist devices when used as a permanent alternative (**destination therapy**) for patients with chronic end-stage heart failure and who are not candidates for heart transplantation **meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage when **ALL** of the following conditions are met:

- New York Heart Association (NYHA) Class IV heart failure not responding to optimal medical management for at least 60 days, or NYHA Class III/IV for at least 28 days, received ≥ 14 days support with an intra-aortic balloon pump or dependent on intravenous (IV) inotropic agents, with 2 failed weaning attempts; **AND**
- Left ventricular ejection fraction (LVEF) $< 25\%$; **AND**

In addition, patients must not be candidates for human heart transplant for one or more of the following reasons:

- Age > 65 years; **or**
- Insulin-dependent diabetes mellitus with end-organ damage; **or**
- Chronic renal failure with serum creatinine > 2.5 mg/dl for ≥ 90 days; **or**
- Other clinically significant condition.

Other Indications

Ventricular assist devices for conditions other than those listed above do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Use of a non-FDA approved ventricular assist device does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and Technology Evaluation Criteria (TEC) and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was updated with searches of the MEDLINE database. The most recent literature search was performed for the period from July 2011 through July 2012. The literature review focuses on three types of devices: 1) left ventricular assist devices (LVAD), 2) total artificial hearts (TAH), and 3) percutaneous ventricular assist devices (pVAD). The literature review addresses short-term use of the devices as a bridge to recovery or transplantation. The 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.

Left Ventricular Assist Devices

Bridge to Recovery: Post-cardiotomy Setting

Five studies of the Centrimag RVADS included between 12 and 32 patients, the majority of whom received biventricular devices. Indications (and numbers of patients) in these five studies were: support for postcardiotomy cardiogenic shock (bridge to long-term device implantation (n=9), treatment of right heart failure in patients who previously received LVADs (n=15), bridge to later decision when neurologic status is clarified (n=16), and acute donor graft failure (n=6). 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 83%. Major complications included bleeding requiring reoperation, sepsis, and stroke. No device failures were observed in these studies.

Bridge to Transplant: Left Ventricular Assist Devices

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 post-transplant survival, thus improving

the use of donor hearts. Currently available implantable LVADs consist of pulsatile devices that require stiff power vent lines that perforate the skin and implantable pump chambers, as well as non-pulsatile axial flow systems of smaller size and lower noise levels.

In five reports, with samples ranging from 32 to 279 patients, most participants received the continuous-flow device as a bridge to transplantation. Survival rates at six months were between 67% and 87%, and between 50% and 80% at one year. These rates are similar to those observed in a recent report of a federal circulatory support device registry. A study by Patel and colleagues 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. Serious adverse events occurring after HeartMate II-implantation include bleeding episodes requiring reoperation, stroke, infection, and device failure.

A systematic review published in 2012 examined the evidence on the effect of LVADs on post-transplant outcomes. This review included 31 observational studies that compared outcomes of transplant in patients who did and did not have pre-transplant LVAD. Survival at one year was more likely in patients who had LVAD treatment, but this benefit was confined to patients who received an intra-corporeal device (relative risk [RR]: 1.8, 95% confidence interval [CI]: 1.53-2.13). For patients treated with an extracorporeal device, the likelihood of survival was not different from patients who were not treated with an LVAD (RR: 1.08, 95% CI: 0.95-1.22). There was no difference in the risk of rejection between patients who did and did not receive LVAD treatment.

There is one FDA-approved device via the Humanitarian device Exemption (HDE) process available for use as a bridge to cardiac transplant in children. This HDE approval was based on data from children who were a part of the initial clinical studies of this device. Publications have reported positive outcomes for children as VADs as a bridge to transplantation. Using the United Network for Organ Sharing (UNOS) database, Davies reported on use of Davies reported on use of VADs in pediatric patients undergoing heart transplantation. Their analysis concluded that pediatric patients requiring a pre-transplantation VAD have similar long-term survival to those not receiving mechanical circulatory support.

Contraindications to transplantation include conditions that would normally exclude patient from heart transplant:

- Chronic irreversible hepatic, renal, or respiratory failure.
- Systemic infection.
- Blood dyscrasia.

In 2011, Streuber et al published a case series of 50 patients awaiting heart transplantation treated with a newer generation HeartWare® VAD. This device was smaller than previous versions, and implanted within the pericardial space. Patients were followed until transplantation, myocardial recovery, device explant, or death. The median duration of time on the LVAD was 322 days. Nine patients died, three from sepsis, three from multiple organ failure, and three from hemorrhagic stroke. At the end of follow-up, 20 patients had undergone transplant (40%), four had the pump explanted (8%), and the remaining 17 continued on pump support (34%). The most common complications were infection and bleeding. A total of 21 patients had infections

(42%), and five patients had sepsis (10%). Bleeding complications occurred in 15 patients (30%), ten of whom (20%) required surgery for bleeding.

Conclusions

The evidence on the efficacy of LVADs as bridge to transplant consists of numerous uncontrolled trials of patients who have no other treatment options. These studies report that substantial numbers of patients survive 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 pre-transplant LVADs on survival from transplant is uncertain, with some studies reporting worse survival in patients receiving LVADs, but other studies reporting similar or improved survival.

Destination Therapy: Left Ventricular Assist Device

The REMATCH study published results in late 2001 and was responsible for ultimate FDA approval of the Thoratec left ventricular assist device for end stage heart failure for patients who are not candidates for heart transplantation. In this randomized trial, 68 patients received the left ventricular device and 61 patients were placed on optimal medical management. The rates of survival after one year were 52 percent in the device group and 25 percent in the medical therapy group. After two years the survival rate in the device group was 23 percent and the medical-management group was eight percent. There was a significantly higher occurrence of adverse events in the device group due to infection, bleeding, and malfunction of the device. The quality of life was significantly improved at one year in the device group. In conclusion, the left ventricular assist device provided a clinically significant improvement in survival and quality of life for those with severe heart failure and therefore not candidates for cardiac transplantation.

In a December 2002 TEC assessment, it was noted that the use of left ventricular assist devices for destination therapy for patients with severe heart failure and are not candidates for cardiac transplantation and meet the criteria from the REMATCH trial meets TEC criteria for coverage.

The policy regarding LVADs 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 quality of life 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 two-year follow up of patients in the REMATCH trial, which found that survival and quality of life benefits were still apparent. In addition, this study and other case series suggest continuing improvement in outcomes related to ongoing improvements in the device and patient management. 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.

Conclusions

The main piece of evidence on the efficacy of LVADs as destination therapy in patients who are not transplant candidates is from a multicenter randomized controlled trial (RCT), the REMATCH study. This trial 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 for 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. 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 a two-year survival, free of disabling stroke or need for device replacement. Continuous-flow devices (n=134) reached the primary outcome at a rate of 46% (95% confidence interval [CI] 38-55) compared to pulsatile-flow patients (n=66) rate of 11% (95% CI 3-18), which was a significant difference (p<0.001). Analysis of constituent factors indicated that a lower rate of devices needing replacement in the continuous-flow group had the largest effect on the composite endpoint; two-year death rate also favored this device (58% vs. 24%, p=0.008). Stroke and death (within two years of implantation) were similar in the two groups (stroke rate 12% and death rate 36%). Quality of life scores were also similar in the two groups. Although unblinded, this randomized trial adds to the evidence favoring continuous-flow devices.

Nativi et al in 2011 published a non-randomized comparison of pulsatile versus continuous flow devices using data from the registry of the International Society for Heart and Lung Transplantation on 8,557 patients undergoing transplant. Comparisons were made among patients receiving a pulsatile LVAD, a continuous flow LVAD, and no LVAD. Two time periods were used for analysis, the first was pre-2004, when nearly all LVADs were pulsatile devices, and post-2004 when continuous use devices began to be used in clinical care. Comparing the first time period to the second time period, there was a significantly greater risk of mortality in the first time period compared to the second time period (relative risk [RR]: 1.30, 95% CI 1.03-1.65, p=0.03). When analysis was confined to the second time period, there was no significant improvement in survival for the continuous group compared to the pulsatile group (RR: 1.25, 95% CI: 1.03-1.65, p=0.03).

Other non-randomized studies that have compared outcomes from different types of LVADs have been smaller and/or focused on physiologic outcomes. 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.

Conclusions

The evidence on the comparative efficacy of different devices consists of one RCT and several non-randomized comparative studies. The RCT reported fairly large differences in a composite outcome measure favoring the continuous flow devices, with increases in revision and reoperation rates for the pulsatile device group being the largest factor driving the difference in outcomes. Other non-randomized comparative studies, including one database study with large numbers of patients, have not reported important differences between devices on clinical outcomes.

Total Artificial Heart Bridge to Transplant

The FDA approval of the CardioWest TAH was based on the results of a nonrandomized, prospective study of 81 patients. Patients had failed inotropic therapy and had biventricular failure and thus were not considered appropriate candidates for an LVAD. The rate of survival to transplant was 79%, which was considered comparable to the experience with LVAD in patients with left ventricular failure. The mean time from entry into the study until transplantation or death was 79.1 days.

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

Destination Therapy: Total Artificial Hearts

Data concerning the artificial heart are available from information concerning the FDA approval and from a published article describing results for the first seven patients. The FDA indicated that their 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 one-month survival prognosis of not more than 30%, were not eligible for cardiac transplants, and were felt to not benefit from VAD therapy. The study was reported to show that the device is safe and has likely benefit for people with severe heart failure whose death is imminent and for whom no alternative treatments are 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 one patient. Six patients were ambulatory; one patient was discharged home. Complications included postoperative bleeding and neurological events. Device-related infection was "non-existent."

This device shows technological progress, and these initial results are encouraging; however, a number of questions remain. These questions may be answered once the results of the 14-patient study are published, or data on a larger group of patients may be needed. One issue is to further

analyze relevant patient outcomes (complications, quality of life, survival, etc). Therefore based on current information, this device is considered investigational.

Conclusions

There is a smaller amount of evidence on the use of TAH as a bridge to transplantation, or as destination therapy, compared to 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. There is insufficient evidence on the use of TAH as destination therapy to support conclusions.

Percutaneous Ventricular Assist Devices (pVAD)

Dixon et al published the results of the PROTECT I trial that evaluated the feasibility and effectiveness of the Impella 2.5 circulatory assist device in high-risk PCI procedures. The prospective, multicenter study trial had 20 patients with poor left ejection fraction (< 35%) that underwent high-risk PCI on an unprotected left main coronary artery or last patent coronary conduit with minimally invasive circulatory support employing the Impella 2.5 system. The primary efficacy end point was freedom from hemodynamic compromise during PCI and the primary safety end point was the incidence of major adverse cardiac events at 30 days. The Impella device was implanted in all patients. At 30 days, the incidence of major adverse cardiac events was 20% (two had a periprocedural myocardial infarction; two patients dies at days 12 and 14. None of the patients developed hemodynamic compromise during PCI. The authors concluded that the Impella 2.5 system is safe, easy to implant, and provides excellent hemodynamic support during high-risk PCI. (The PROTECT Trial; NCT00534859)

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 endpoint was the composite of ten different complications occurring within 40 days of the procedure, with the authors hypothesizing a 10% absolute decrease in the complication rate for patients in the pVAD group. The trial was discontinued prematurely in late 2010 due to futility, after an interim analysis revealed that the primary endpoint could not be reached. At this point, approximately half the planned patients had been enrolled. Interim results were presented at the 2011 American College of Cardiology (ACC) scientific meeting. These results reported composite adverse event rates of 38% in the pVAD group compared to 43% in the IABP group (p=0.40).

A few other case series have described pVAD use in high-risk patients undergoing an invasive cardiac procedure. Sjauw et al performed a retrospective analysis of 144 consecutive patients undergoing high-risk PCI with pVAD support (Impella® system) from a European registry. Endpoints included successful device function and incidence of adverse events at 30 days. The device was successfully implanted in all 144 patients. There was one periprocedural death and eight 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 were one stroke (0.7%) and no MIs reported.

Kar et al reported on five patients who were treated with pVAD support during percutaneous coronary intervention. All patients were ineligible for CABG because of severe comorbidities. In four of five patients, the procedure was performed successfully and the pVAD removed within several hours. In the fifth patient, persistent cardiogenic shock precluded removal of the pVAD for more than 48 hours and the patient eventually died of progressive heart failure ten days after pVAD was discontinued. Giombolini et al treated six patients with pVAD who were undergoing a high-risk cardiac procedure. Three cases were performed on an emergency basis and three were performed on an elective basis. There were no deaths and all six procedures were completed successfully.

Summary

There is a substantial body of evidence from clinical trials and observational studies supporting implantable ventricular assist devices as a bridge to transplant in patients with end-stage heart failure, possibly improving mortality as well as quality of life. A well-designed clinical trial, with two years of follow-up data, demonstrates an advantage of implantable ventricular assist devices as destination therapy for patients who are ineligible for heart transplant. Despite an increase in adverse events, both mortality and quality of life appear to be improved for these patients. Therefore, LVADs may be considered medically necessary as a bridge to transplant and as destination therapy in patients who are not transplant candidates.

The evidence for total artificial heart in these settings is less robust. However, given the limited evidence from case series and the lack of medical or surgical options for these patients, 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 an LVAD. TAH may be considered medically necessary for this purpose. There is insufficient evidence on the use of TAH as destination therapy, and TAH is considered investigational for this purpose.

The evidence on percutaneous ventricular assist devices (pVADs) does not support that these devices improve health outcomes. Three randomized controlled trials 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, and a fourth RCT was terminated early due to futility. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series cannot determine if pVAD improves mortality, and high rates of complications are reported with pVAD use. Because of the lack of demonstrated benefits in clinical trials, and the high complication rates reported, the use of pVAD for all indications is considered investigational.

Technology Assessments, Guidelines and Position Statements

The American College of cardiology/American Heart Association (ACC/AHA) released a guideline to the management of end-stage heart failure in 2005, a 2009 focused updated did not change any recommendations regarding the technologies covered in this policy. The group has stated that left ventricular assist device may be indicated in a highly select group of patients who are not candidates for heart transplantation and are likely to have a one year survival rate of less than 50% with medical therapy alone. The short-term use of any form of mechanical ventricular

support is mentioned as an area of research interest. No recommendations are made regarding this indication.

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 left ventricular assist devices:

- 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)

The European Society of Cardiology published guidelines in 2008 for the diagnosis and treatment of acute and chronic heart failure. A focused update was published in 2010. These guidelines included the following statements about LVADs:

- Current indications for LVADs and artificial hearts include bridging to transplantation and managing patients with acute, severe myocarditis (Class IIa recommendation, level of evidence C).
- LVAD may be considered as destination therapy to reduce mortality in patients with severe heart failure who are ineligible for transplant. (Class IIb recommendation, level of evidence B).

Key Words:

Ventricular assist device, biventricular support, cardiac support, heart transplantation (transplant), LVAD, VAD, destination therapy, HeartWare, Impella 2.5, Impella 2.5 circulatory assist device, DeBakey, percutaneous ventricular assist device, pVAD, TandemHeart[®], EXCORE

Approved by Governing Bodies:

FDA approved: Abiomed BVS 5000, 1992; HeartMate 10001P, 1994; Thoratec, 1994; Novacor LVAS, 1998; HeartMate Vented Electric Left Ventricular System, 1998. Thoratec HeartMate Destination Therapy approved November 2002, DeBakey VAD Child, February 25, 2004; CardioWest Total Artificial Heart for Bridge to Transplant, October 18, 2004; Thoratec HeartMate II Left Ventricular Assist System, April 21, 2008.

EXCORE Pediatric system received Humanitarian Device Exemption status on December 17, 2011 for use by pediatric patients with severe isolated left ventricular or bi-ventricular dysfunction who are candidates for cardiac transplant and require circulatory support. TandemHeart® system by CardiacAssist, Inc received a 510(k) clearance from the FDA Sept 2005

Impella 2.5 system by Abiomed received a 510(k) clearance from the FDA June 2008

Heartmate II by Thoratec received premarket approval on January 20, 2010 for destination cardiac support for patients with advanced-stage heart failure who are ineligible for transplantation. It was previously approved as an interim device (see above).

HeartWare Ventricular Assist System , a left ventricular assist device (LVAD), received FDA approval on November 20, 2012 to support heart function and blood flow in patients with end-stage heart failure who are awaiting a heart transplant.

Total Artificial Heart

The temporary Cardiowest™ Total Artificial Heart (TAH-t) is intended for use inside the hospital. In April of 2010, the FDA approved a name-change to “Syncardia Temporary Total Artificial Heart.”

The “AbioCor® Implantable Replacement Heart System” (AbioMed, Inc., Danvers MA) was approved by the FDA the Humanitarian Device Exemption (HDE) process on September 5, 2006 for use in severe bi-ventricular end-stage heart disease individuals who are not cardiac transplant candidates and who:

- Are less than 75 years of age
- Require multiple inotropic support
- Are not treatable by 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 about 90% of women and for many men. The FDA is requiring the company to provide a comprehensive patient information package to patients and families. To further refine and improve and improve the use of this artificial heart technology, Abiomed will conduct a post-marketing study of 25 additional patients. The post-market study was recommended by the Circulatory Systems Devices Panel, a part of the FDA’s Medical Devices Advisory Committee.

Ventricular Assist Devices

In December 1995, device Thoratec® Ventricular Assist Device System (Thoratec Corp., Pleasanton, CA) was approved by the FDA through the premarket approval 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 the above 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, the FDA approved the DeBakey VAD® Child under the HDE approval process. According to the FDA, this device is indicated under HDE for both home and hospital use for children who are between ages 5 and 16 years and 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 the FDA through the premarket approval 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 (NYHA) Class IIIB or 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 the 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 November 2012, device HeartWare Ventricular Assist System (HeartWare, Inc., Framingham, Mass.) was approved by the FDA using the INTERMACS registry as a control. INTERMACS registry was established in 2005 as a joint effort involving the FDA, National Heart, Lung and Blood Institute (NHLBI), Centers for Medicare and Medicaid Services (CMS), clinicians, scientists, and industry. This was the first time the FDA approved an LVAD using registry data as a control. INTERMACS is managed by the University of Alabama at Birmingham.

Percutaneous Ventricular Assist Devices (circulatory assist devices)

The Impella® Recover LP 2.5 Percutaneous Cardiac Support System (Abiomed, Aachen, Germany) received FDA 510(k) approval in May 2008 for short-term (less than 6 hours) use in

patients requiring circulatory support. The TandemHeart® (Cardiac Assist, Pittsburgh) received a similar 510(k) approval for short-term circulatory support in September 2005.

VAD Device	Manufacturer	Date of Initial Approval	Method of FDA clearance	Indication
Thoratec® IVAD	Thoratec	August 2004	PMA Supplement	Bridge to Transplant and Post-cardiotomy
DeBakey VAD® Child	MicroMed	April 2004	Humanitarian Device Exemption	Bridge to Transplant in children 5–16 years of age
HeartMate II®	Thoratec	April 2008	PMA	Bridge to Transplant and Destination
Centrimag®	Levitronix	October 2008	HDE	Postcardiotomy
HeartWare	HeartWare Inc.	November 2012	510(k)	Bridge to Transplant
Impella®	Abiomed	May 2008	510(k)	Partial circulatory support using an extracorporeal bypass control unit. for periods up to 6 hours
TandemHeart®	Assist	September 2005	510(k)	Temporary left ventricular bypass of 6 hours or less

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT codes:

- 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
- 33976** Implantation 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 ventricle
- 33981** Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
- 33982** Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
- 33983** Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
- 33990** Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
- 33991** Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transeptal 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
- 33975** Implantation of ventricular assist device; extracorporeal, single ventricle
- 93750** Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report

ICD-9 codes:

- 398.91** Rheumatic heart failure (congestive)
- 402.01** Malignant hypertensive heart disease with congestive heart failure
- 402.11** Benign hypertensive heart disease with congestive heart failure
- 404.01** Hypertensive heart and chronic kidney disease, malignant, with congestive heart failure and with chronic kidney disease stage I through IV, or unspecified

- 404.03** Hypertensive heart and chronic kidney disease, malignant, with congestive heart failure and with chronic kidney disease stage V or end stage renal disease
- 404.11** Hypertensive heart and chronic kidney disease, benign, with congestive heart failure and with chronic kidney disease stage I through stage IV, or unspecified
- 428.0** Congestive heart failure

ICD-10-CM (effective 10/1/14)

- 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
- I50.1-I50.9** - Heart failure code range
- I97.0** Postcardiotomy syndrome

Previous Codes

- 0048T** Implantation of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation
- 0049T** Prolonged extracorporeal percutaneous transseptal ventricular assist device, greater than 24 hours, each subsequent 24-hour period
- 0050T** Removal of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation

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Policy History:

TEC, March 1999

Medical Policy Administration Committee, February 2002

Medical Review Committee, March 2004

Medical Policy Group, May 2004 (1)

Medical Review Committee, May 2004

Medical Policy Administration Committee, June 2004

Available for comment June 28-August 11, 2004

Medical Policy Group, March 2006 (1)

Medical Policy Group, April 2008 (2)

Medical Policy Group, August 2009 (1)

Medical Policy Administration Committee, September 2009

Available for comment September 4-October 19, 2009

Medical Policy Group, October 2010 (1): Description, Key Points and Governing Body Approval updated

Medical Policy Group, November 2010 Reference Update

Medical Policy Administration Committee November 2010

Available for comment November 4 – December 20, 2010

Medical Policy Group, September 2011 (1): Update to Description, Key Points and References; Entire policy reformatted, no changes to policy statements

Medical Policy Group, December 2011 (3): Update to Approved by Governing Bodies & References (FDA Approval of EXCORE)

Medical Policy Group, March 2012 (3): Updated coverage for total artificial heart for bridge to transplant. Added other specialty recommendations and references.

Medical Policy Administration Committee March 2012

Available for comment March 15 – April 30, 2012

Medical Policy Group, November 2012 (3): 2012 Update to Key Points, Governing Bodies, and References

Medical Policy Group, November 2012: 2013 Coding Update-Added Codes 33990 - 33993; deleted Codes 0048T & 0050T effective 1/1/2013

Medical Policy Group, December 2012 (3): Update to Approved by Governing Bodies & References (FDA Approval of HeartWare)

Medical Policy Group, December 2012 (3): 2013 Coding update – Verbiage change to Code 93750-added “or other qualified health care professional”

Medical Policy Panel, February 2013

Medical Policy Group, February 2013 (3): Updated policy statement on children – amended age range from 5-16 years to 0-16 reflecting approval of the BERLIN heart EXCOR device for pediatric patients age 0-16; and clarified info on Medicare-approved heart transplant facility requirement for total artificial hearts; and Medicare-approved heart transplant facility OR Medicare-approved VAD destination facility requirement for VADs

Medical Policy Administration Committee March 2013

Available for comment March 12 through April 25, 2013

Medical Policy Group, August 2013 **(4)**: Added verbiage to BTT policy section “Or a patient who is undergoing evaluation to determine candidacy for heart transplantation.

Medical Policy Administration Committee August 2013.

Available for comment August 22 through October 5, 2013

Medical Policy Group, February 2014 **(5)**: Added ICD-9 and ICD-10-CM diagnosis under Coding; no change to policy statement.

Medical Policy Panel, February 2014

Medical Policy Group, February 2014 **(4)**: Updated description. NO changes to the policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.