MEDICAL POLICY

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POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

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I. POLICY

Post-cardiotomy Setting/Bridge to Recovery

Implantable ventricular assist devices with FDA approval or clearance may be considered **medically necessary** in the post-cardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

Bridge to Transplantation

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

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

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

Destination Therapy

Implantable ventricular assist devices with FDA approval or clearance may be considered **medically necessary** as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following "REMATCH Study" criteria:

- New York Heart Association (NYHA) class IV heart failure for >60 days, OR
- Patients in NYHA class III/IV for 28 days, received >14 days' support with intra-aortic balloon pump or dependent on IV inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for 1 or more of the following reasons:

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

- Age >65 years; OR
- Insulin-dependent diabetes mellitus with end-organ damage; OR
- Chronic renal failure (serum creatinine >2.5 mg/dL for >90 days; OR
- Presence of other clinically significant condition

Other Indications

Other applications of implantable ventricular devices or total artificial hearts are considered **investigational**, including, but not limited to, the use of total artificial hearts as destination therapy.

The use of non-FDA approved or cleared implantable ventricular assist devices or total artificial hearts is considered **investigational.**

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

Policy Guidelines

Only two ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration (FDA) for the pediatric population. The DeBakey VAD® Child device and the Berlin Heart EXCOR Pediatric VAD have FDA approval through the humanitarian device exemption (HDE) process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant, i.e., as a bridge to transplant while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support.

In general, candidates for bridge-to-transplant implantable ventricular assist devices (VADs) are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of <2.0 L/min/m while receiving maximal medical support. Patients with VADs are classified by the United Network for Organ Sharing (UNOS) as Status I, that is, persons who are most ill and are considered the highest priority for transplant.

The median duration for time on the device is between 20 and 120 days.

Contraindications for bridge to transplant VADs and TAH include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders, and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or TAH, implantation is also contraindicated in patients with uncorrected valvular disease.

In addition, individuals must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest™ temporary Total Artificial Heart, this excludes

individuals with body surface areas less than 1.7 m^2 or who have a distance between the sternum and 10^{th} anterior rib of less than 10 cm as measured by CT [computed tomography] scan

Cross-reference:
MP-9.014 Heart Lung Transplant
MP-9.007 Heart Transplant and Laboratory Tests for Heart Transplant Rejection

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] FEP PPO**
[Y] SeniorBlue*
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] SeniorBlue PPO*

* For coverage of artificial hearts and related devices, refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 20.9 Artificial Hearts and Related Devices

** Regarding Ventricular Assist Devices- Refer to FEP Medical Policy Manual MP-7.03.11 Implantable Ventricular Assist Devices. The FEP Medical Policy manual can be found at: http://www.fepblue.org/medical-policies.jsp

** Regarding artificial hearts - implants of artificial organs including those implanted as a bridge to transplant and/or as destination therapy are not covered.

III. DESCRIPTION/BACKGROUND

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.

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. (1) 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 cardiotomy affecting the ventricular wall may preclude VAD use.

Intra-aortic balloon pumps are outside the scope of this policy.

Regulatory Approval

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

Total Artificial Heart

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

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

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

In addition to meeting other criteria, patients who are candidates for the AbioCor® TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men. The FDA is requiring the company to provide a comprehensive patient information package to patients and families. To further refine and improve the use of this artificial heart technology, AbioMed will conduct a postmarketing study of 25 additional patients. The postmarket 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.

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

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

IV. RATIONALE

This policy is regularly 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 2 types of devices: 1) left ventricular assist devices (LVAD) and 2) total artificial hearts. 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

LVADs as Bridge to Recovery: Post-cardiotomy Setting

Five studies of the Centrimag Right Ventricular Assist Device (RVADs) included between 12 and 32 patients, the majority of whom received biventricular devices. (2-4) Indications (and numbers of patients) in these 5 studies were: support for post-cardiotomy cardiogenic shock (bridge to recovery, n=53), bridge to long-term device implantation (n=9), treatment of right heart failure in patients who previously received left ventricular assist devices (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 63%. The proportion of patients discharged from the hospital was between 30% and 83%. Major complications included bleeding requiring reoperation, sepsis, and stroke. No device failures were observed in these studies.

LVADs as Bridge to Transplant

A 1996 TEC Assessment concluded that left ventricular assist devices (LVADs) can provide an effective bridge to transplantation. (5) Goldstein and colleagues published a more recent review. (6) It should be recognized that LVADs do not change the number of patients undergoing heart transplantation due to the fixed number of donor hearts. However, the VAD will categorize its recipient as a high-priority heart transplant candidate.

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. (7-10) 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. (11)

In 5 reports, with samples ranging from 32 to 279 patients, most participants received the continuous-flow device as a bridge to transplantation. (12-16) Survival rates at 6 months were between 67% and 87%, and between 50% and 80% at 1 year. These rates are similar to those

observed in a recent report of a federal circulatory support device registry. (17) A study by Patel and colleagues compared HeartMate I and HeartMate II recipients at a single center, finding the same 1-year survival and similar rates of subsequent development of right heart failure. (15) 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. (18) 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 U.S. Food and Drug Administration (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. (19) Publications have reported positive outcomes for children using ventricular assist devices (VADs) as a bridge to transplantation. Using the United Network for Organ Sharing (UNOS) database, Davies et al. reported on use of VADs in pediatric patients undergoing heart transplantation. (20) Their analysis concluded that pediatric patients requiring a pretransplantation VAD have similar long-term survival to those not receiving mechanical circulatory support.

In 2011, Strueber et al. (21) 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; 3 from sepsis, 3 from multiple organ failure, and 3 from hemorrhagic stroke. At the end of follow-up, 20 patients had undergone transplant (40%), 4 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 5 patients had sepsis (10%). Bleeding complications occurred in 15 patients (30%), 10 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.

LVADs as Destination Therapy

The policy regarding LVADs as destination therapy is based on a 2002 TEC Assessment (22) 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. (23) 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 and colleagues published an extended 2-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 in patient management. (24, 25) However, the durability of the HeartMate device used in the REMATCH trial is a concern; for example, at one participating institution, all 6 long-term survivors required device change-outs. Next generation devices consisting of smaller continuous flow devices are eagerly anticipated.

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 and colleagues published data from an unblinded randomized multicenter trial comparing a continuous flow device with a pulsatile device. (26) Subjects were randomly assigned to continuous-flow or pulsatile-flow devices on a 2:1 block-randomization basis. The primary outcome measured was a composite endpoint of 2-year survival, free of disabling stroke or need for device replacement. Continuous-flow patients (n=134) reached the primary outcome at a rate of 46% (95% CI: 38-55) compared to pulsatile-flow patients' (n=66) rate of 11% (95% CI: 3-18), which was a significant difference

(p<0.001). Analysis of constituent factors indicated that a lower rate of devices needing replacement in the continuous-flow group had the largest effect on the composite endpoint; 2-year death rate also favored this device (58% vs. 24%, respectively; p=0.008). Stroke and death (within 2 years of implantation) were similar in the 2 groups (stroke rate 12% and death rate 36%). Quality-of-life scores were also similar in the 2 groups. Although unblinded, this randomized trial adds to the evidence favoring continuous-flow devices.

Nativi et al. (27) 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. (28-31) 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

TAH as Bridge to Transplant

The FDA approval of the CardioWest TAH was based on the results of a nonrandomized, prospective study of 81 patients. (32) 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. (33) 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 1, 5, and 10 years, respectively, was 76.8%, 60.5%, and 41.2%.

TAH as Destination Therapy

Data concerning the artificial heart are available from information concerning the FDA approval (34) and from a published article describing results for the first 7 patients. (35) 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 1-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 1 patient. Six patients were ambulatory; 1 patient was discharged home. Complications included postoperative bleeding and neurologic 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.

Ongoing trials (all devices)

The BERLIN Heart EXCOR IDE study (47) is a prospective multicenter, single-arm trial of the EXCOR device in small children aged 0-16 years with severe heart failure meeting the criteria for transplantation. This is the only device that is FDA-approved for children younger than 5 years of age. The primary efficacy endpoint of this trial is survival to recovery or heart

transplant, and the primary safety endpoint is the incidence of serious adverse events. A total of 48 children are planned to be enrolled. The study population will be compared to historical controls treated with extra-corporeal membrane oxygenation (ECMO).

Summary

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. 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 2 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.

Practice 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 (48); a 2009 focused update did not change any recommendations regarding the technologies covered in this policy. (49) The group has stated that left ventricular assist devices may be indicated in a highly select group of patients who are not candidates for heart transplantation and are likely to have a 1-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. (50) 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. (19) A focused update was published in 2010. (51) 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).

V. DEFINITIONS

CARDIOTOMY refers to an incision of the heart**.**

DESTINATION THERAPY refers the intention of permanent use.

NEW YORK HEART ASSOCIATION CLASS III refers to patients with cardiac disease which results in marked limitation of physical activity. These patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.

NEW YORK HEART ASSOCIATION CLASS IV refers to patients with cardiac disease which results in the inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable

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IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
0051T	0052T	0053T	33975	33976	33977	33978	33979	33980

HCPCS Code	Description
Q0480	DRIVER FOR USE WITH PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0481	MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0482	MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC/PNEUMATIC COMBINATION VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0483	MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

HCPCS Code	Description
Q0484	MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0485	MONITOR CONTROL CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0486	MONITOR CONTROL CABLE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0487	LEADS (PNEUMATIC/ELECTRICAL) FOR USE WITH ANY TYPE ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0488	POWER PACK BASE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0489	POWER BACK BASE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0490	EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0491	EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0492	EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0493	EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0494	EMERGENCY HAND PUMP FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0495	BATTERY/POWER PACK CHARGER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0496	BATTERY ELEC/COMBO VAD, REP
Q0497	BATTERY CLIPS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0498	HOLSTER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0499	BELT/VEST FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0500	FILTERS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0501	SHOWER COVER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0502	MOBILITY CART FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY
Q0503	BATTERY FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, EACH
Q0504	POWER ADAPTER FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, VEHICLE TYPE
Q0506	BATTERY, LITHIUM-ION, FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

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POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

ICD-9-CM Diagnosis Code*	Description
398.91	RHEUMATIC HEART FAILURE (CONGESTIVE)
402.01	MALIGNANT HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
402.11	BENIGN HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
404.01	HTN HRT & CKD MAL W/HF & W/CKD STAGE 1-IV/UNS
404.03	HTN HRT & CKD MALIG W/HF & W/CKD STAGE V/ESRD
404.11	HTN HRT & CKD BEN W/HF & W/CKD STAGE I-IV/UNS
428.0	CONGESTIVE HEART FAILURE, UNSPECIFIED

The following ICD-10 diagnosis codes will be effective October 1, 2014

ICD-10-CM Diagnosis Code*	Description
109.81	RHEUMATIC HEART FAILURE (CONGESTIVE)
I11.0	HYPERTENSIVE HEART DISEASE WITH HEART FAILURE
I13.0	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE WITH HEART FAILURE STAGE 1 THROUGH STAGE 4 CHRONIC KIDNEY DISEASE, OR UNSPECIFIED CHRONIC KIDNEY DISEASE
I113.2	HYPERTENSIVE HEART AND CHRONIC KIDNEY DISEASE WITH HEART FAILURE WITH STAGE 5 CHRONIC KIDNEY DISEASE, OR END STAGE RENAL DISEASE
I150.1-I50.9	HEART FAILURE CODE RANGE
I97.0	POSTCARDIOTOMY SYNDROME

*If applicable, please see Medicare LCD or NCD for additional covered diagnosis

X. POLICY HISTORY

MP 1.026	**CAC 2/25/03**
	CAC 4/27/04
	CAC 10/26/04
	CAC 10/25/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 1/29/08
	CAC 1/27/09
	CAC 1/26/10 Consensus review
	CAC 4/26/11 Adopted BCBSA, No change to policy statements. Changed title. Additional criteria was listed for coverage of artificial hearts including no other treatment options, ineligible for ventricular support devices, currently listed as heart transplant

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POLICY TITLE	TOTAL ARTIFICIAL HEARTS AND IMPLANTABLE VENTRICULAR ASSIST DEVICES
POLICY NUMBER	MP-1.026

	candidates and not expected to survive until a donor heart is available. For ventricular assist devices additional criteria includes patients who are transplant candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for transplant. Added coverage criteria for coverage of VADs for children age 5-16. Deleted criteria for peak O2 consumption. Medicare variation updated.
	CAC 6/26/12 Investigational statement added for percutaneous ventricular assist devices.
	11/1/12 Due to provider feedback, administrative changes made regarding pVADs. Deleted statement "Percutaneous ventricular assist devices (pVADs) are considered **investigational** for all indications". Changed FEP variation to reference FEP Medical Policy Manual MP-7.03.11 Implantable Ventricular Assist Devices.
	7/29/13 Admin coding review complete--rsb
	CAC 9/24/13 Minor review. Policy statement on children amended; age range changed from 5-16 to 0-16, reflecting the approval of the BERLIN heart EXCOR device for pediatric patients aged 0-16. Added Rationale section. Updated references. Added policy guidelines section.

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