



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Ventricular Assist Devices (VADs)

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Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	14
References	16
Policy History	21

Hyperlink to Related Coverage Policies

- External Counterpulsation
- Heart Transplantation
- Partial Left Ventriculectomy, Dynamic
Cardiomyoplasty and Ventricular
Reshaping in the Treatment of Heart
Failure
- Total Artificial Heart

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers a U.S. Food and Drug Administration- (FDA-) approved ventricular assist device (VAD) as medically necessary when used in accordance with device-specific, FDA-approved indications and contraindications when EITHER of the following criteria is met:

- as a bridge to recovery for individuals with acute cardiogenic shock, acute myocarditis, or for individuals following cardiac surgery who cannot be weaned from cardiopulmonary bypass
- as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from left ventricular heart failure

CIGNA covers a U.S. FDA-approved VAD as medically necessary when used as destination therapy for individuals who are not candidates for heart transplantation when ALL of the following criteria are met:

- New York Heart Association (NYHA) Class IV end-stage left ventricular heart failure
- left ventricular ejection fraction (LVEF) < 25%
- demonstrated functional limitations, with a peak oxygen consumption of <14 milliliters per kilogram of body weight per minute
- failure of optimal medical therapy according to EITHER of the following device-specific parameters:

- HeartMate® XVE-LVAS (Thoratec Corp., Pleasanton, CA): individual has failed to respond to optimal medical therapy for at least 60 of the last 90 days
- HeartMate II® (Thoratec Corp., Pleasanton, CA): individual has failed to respond to optimal medical therapy for 45 of the last 60 days, or dependence on intra-aortic balloon pump for a period of seven days, or inotropes for a period of at least fourteen days

CIGNA covers the CentriMag® Right Ventricular Assist System (RVAS) as medically necessary for temporary circulatory support when used in accordance with the FDA's Humanitarian Device Exemption (HDE) requirements when BOTH of the following criteria are met:

- device is used for up to fourteen days for individuals in cardiogenic shock due to acute right ventricular failure
- individual is willing and able to be treated with heparin or an appropriate alternative anticoagulation

CIGNA covers the DeBakey VAD® Child Left Ventricular Assist System as medically necessary as a bridge to cardiac transplantation in children when used in accordance with the FDA's Humanitarian Device Exemption (HDE) requirements when ALL of the following criteria are met:

- age 5–16
- body surface area (BSA) $\geq 0.7 \text{ m}^2$ and $< 1.5 \text{ m}^2$
- in NYHA Class IV end-stage (i.e., left ventricular) heart failure refractory to medical therapy
- listed candidate for cardiac transplantation
- none of the following contraindications:
 - primary coagulopathy or platelet disorders
 - anatomical anomalies that would prevent surgical connection of the outflow graft to the ascending aorta
 - right ventricular failure unresolved by medical therapy

CIGNA does not cover percutaneous VADs (e.g., TandemHeart® PTVA® System, Impella Recover® LP 2.5 Percutaneous Cardiac Support System, Impella 5.0 Catheters) because they are considered experimental, investigational or unproven

General Background

Ventricular assist devices (VADs) function to reduce myocardial work by reducing ventricular preload while maintaining systemic circulation. VADs may be extracorporeal, paracorporeal, implantable with percutaneous power support, or fully implantable, and may provide continuous or pulsatile flow. VADs may be employed on a short-term or long-term basis, or as permanent (destination) therapy. VADs may provide left ventricular support (LVAD), right ventricular support (RVAD), or biventricular support (BiVAD).

Short-term VAD use may provide a bridge to recovery for patients in postcardiotomy shock or those with a potentially reversible condition (e.g., acute myocarditis). VADs are also used as a bridge to transplant for patients with heart failure. Heart failure is a complex syndrome that occurs secondary to inherited or acquired abnormalities of cardiac structure and/or function that impair the ability of the left ventricle to eject blood. More than five million people in the United States live with heart failure, and the incidence of heart failure continues to increase, due in part to the expanded aging population and advances in therapeutic management of cardiovascular disease. Transplantation has become the standard treatment for eligible patients with irreversible severe biventricular failure unresponsive to medical or surgical treatment. The supply of donor hearts has decreased in recent years, however, while the demand has increased. As patients become more hemodynamically compromised, there is an increased risk of death prior to transplantation, as well as a less favorable outcome following transplantation. Timely VAD use may restore hemodynamic stability and end-organ function, and allow nutritional support and rehabilitation prior to transplantation (Libby: Braunwald's Heart Disease, 2007; Hunt et al., 2009).

Throughout the 1990s, VADs underwent many modifications to improve reliability and reduce complications, as well as to improve utility and ease of use for patients living with these devices. Their improved reliability and

mobility has resulted in the use of VADs as destination therapy for selected patients who are not candidates for cardiac transplant.

Percutaneous VADs, also referred to as percutaneous circulatory support devices, have been proposed as an alternative to a traditional VAD or intra-aortic balloon pump (IABP) for short-term partial or total hemodynamic support. Unlike traditional VADs used for short-term support, percutaneous VADs are minimally invasive and do not require surgical implantation, and unlike IABP, percutaneous VADs provide hemodynamic support independent of left ventricular function. The IABP requires a residual level of left ventricular function to be effective. Percutaneous VADs have been proposed for use during emergent procedures for patients in acute heart failure caused by left ventricular dysfunction and/or cardiogenic shock. They have also been proposed for use in high-risk percutaneous coronary intervention (PCI) procedures.

The TandemHeart® PTVA® System (CardiacAssist, Inc., Pittsburgh, PA) can be placed using a percutaneous technique, inserting the inflow cannula in the left atrium through the femoral vein and right atrium, and across the interatrial septum. The outflow cannula is placed in the femoral artery. Both cannulae are connected to an extracorporeal miniaturized centrifugal pump. The system provides a flow up to four liters per minute. The Impella Recover® LP 2.5 Percutaneous Cardiac Support System (Abiomed, Inc, Danvers, MA), is a catheter-based pump that can be implanted percutaneously via a cutdown of the femoral or axillary artery or directly into the ascending aorta. The tip of the catheter contains a microaxial flow pump. The catheter is placed in the left ventricle through the aortic valve, and the pump at the tip of the catheter propels blood to the outflow portion of the device in the ascending aorta. The system includes a mobile console in addition to the implantable pump. Placement is performed under transesophageal echocardiography (TEE) or fluoroscopic guidance. The original Impella flows up to 2.5 liters per minute. The Impella 5.0 contains a larger pump, permitting a flow range up to 5 liters per minute. The Impella 5.0 LP is inserted through the femoral artery via cutdown, and the Impella 5.0 LD is inserted through the aorta (Libby: Braunwald's Heart Disease, 2007; Sarkar and Kini, 2010; ECRI, 2010).

The severity of heart failure is a key factor in assessing the need for VAD use. The New York Heart Association functional classification system, below, is the most frequently used measure of heart failure and is included in the FDA approval criteria for most VADs.

- Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- Class IV. Patients with cardiac disease resulting in inability to carry on 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.

Many cardiologists further stratify Class III patients with a sub-classification of IIIA to indicate no dyspnea at rest, and IIIB to indicate recent dyspnea at rest.

U.S. Food and Drug Administration (FDA)

The VADs described below have been granted FDA approval through the premarket approval (PMA) process. Device selection is made based on specific FDA-labeled indications:

Abiomed BVS® 5000 Biventricular Support System/Abiomed AB 5000 Circulatory Support System

(AbioMed Cardiovascular, Inc.): The Abiomed BVS 5000 system received FDA approval through the PMA process on April 6, 1990. On April 28, 2003, FDA approval was provided for the addition of the AB 5000 pneumatic drive console to the BVS 5000 system. The AB 5000 console can be used to drive one or two BVS 5000 blood pumps, and can be used either in the hospital or for transport between hospitals.

The modified device, marketed as Abiomed AB 5000 circulatory support system, received FDA approval through the PMA process on September 24, 2003. According to the approval order statement, it is indicated for use in patients with reversible ventricular dysfunction who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients with acute cardiac disorders leading to hemodynamic

instability. The intent of AB 5000 system therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function.

Thoratec® Ventricular Assist Device (VAD) System (Thoratec Corporation, Pleasanton, CA): The Thoratec VAD received FDA approval through the PMA process on December 20, 1995 as a bridge to transplantation for use in patients with end-stage heart failure who meet all the following criteria:

- candidate for cardiac transplantation
- imminent risk of dying before donor heart procurement
- dependence on or incomplete response to continued vasopressor support

On May 21, 1998, the approved indications were expanded to include use in post-cardiotomy patients who are unable to be weaned from cardiopulmonary bypass.

Thoratec® Paracorporeal Ventricular Assist Device (PVAD™) System and TLC-II Portable VAD Driver: (Thoratec Corporation, Pleasanton, CA): On November 26, 2003 FDA approval was granted to expand the indications for use for the Thoratec VAD System. The modified device is marketed as the Thoratec PVAD System and TLC-II Portable VAD Driver. When used with the portable VAD driver, the device is intended for use for transportation of patients via ground ambulance, fixed wing aircraft or helicopter, and can also be used to allow suitably-qualified patients to take off-site excursions within a two-hour travel radius of the hospital in the company of a trained caregiver.

Thoratec Implantable Ventricular Assist Device (IVAD™) (Thoratec Corporation, Pleasanton, CA): On August 3, 2004, FDA approval was granted for the Thoratec IVAD as an alternative VAD blood pump for use in the approved Thoratec VAD System. The IVAD is designed to be compatible with both the dual driver console and the TLC-II portable VAD driver.

HeartMate® VE-LVAS (Thoratec Corporation, Pleasanton, CA): The HeartMate VE-LVAS received FDA approval through the PMA process on September 29, 1998 as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. It is indicated for use both inside and outside the hospital.

HeartMate® Sutures Not APplied Vented Electric Left Ventricular Assist System (SNAP VE LVAS) (Thoratec Corporation, Pleasanton, CA): On November 6, 2002, the HeartMate SNAP VE LVAS, a revised version of the HeartMate VE-LVAS, received FDA approval through the PMA process for expanded indications. In addition to use as a bridge to transplantation as described above, the HeartMate XVE was approved for patients who meet the following criteria:

- New York Heart Association Class IV end stage left ventricular failure
- received optimal medical therapy for at least 60 of the last 90 days
- life expectancy of less than two years
- not eligible for cardiac transplantation

The device is approved for use both inside and outside the hospital.

HeartMate® XVE-LVAS (Thoratec Corporation, Pleasanton, CA): On April 4, 2003, the HeartMate XVE-LVAS received FDA approval through the PMA process. Approved indications are identical to the approved indications for the SNAP-VE LVAS.

Thoratec HeartMate II® Left Ventricular Assist System (LVAS) (Thoratec Corporation, Pleasanton, CA): The HeartMate II LVAS received FDA approval through the PMA process on April 21, 2008. According to the approval letter, the device is indicated for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. It is intended for use both inside and outside the hospital, or for transportation of VAD patients via ground ambulance, fixed-wing aircraft, or helicopter.

The HeartMate II LVAS is an implanted continuous axial flow pump with external components. Electrical power to the implanted pump is delivered through a percutaneous lead that connects to an external system controller.

The system controller is powered by a power base unit that connects to AC power, or by two batteries carried or worn by the patient. The HeartMate II LVAS, unlike previously approved VADs, is small in size and can be implanted in patients with a body surface area (BSA) less than 1.5 m². PMA approval was based in part on the HeartMate II Bridge to Transplantation Primary Study Cohort, a multi-center non-blinded non-randomized prospective study that demonstrated bridge to transplant rates comparable to currently approved devices.

On January 20, 2010, the HeartMate II indications for use were expanded to allow use in patients who meet the following criteria:

- New York Heart Association Class IIIB or IV end stage left ventricular failure
- received optimal medical therapy for at least 45 of the last 60 days
- life expectancy of less than two years
- not a candidate for cardiac transplantation

The expanded approval for the HeartMate II as destination therapy was based primarily on the results of the study by Slaughter et al., discussed below.

The CentriMag[®] Right Ventricular Assist System (RVAS) (Levitronix LLC, Waltham, MA)

The CentriMag RVAS received FDA Humanitarian Device Exemption (HDE) approval on October 7, 2008. In order to receive HDE approval, a manufacturer must be granted a Humanitarian Use Device (HUD) exemption by demonstrating that the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 people in the U.S. per year. Although data demonstrating the safety and probable clinical benefit are required for HDE approval, clinical trials evaluating the effectiveness of the device are not required. Following HDE approval, the hospital or health care facility institutional review board (IRB) must also approve the use of the device at that institution before the device may be used in a patient.

The CentriMag RVAS is intended to provide temporary circulatory support for up to fourteen days for patients in cardiogenic shock due to acute right ventricular failure. The device is contraindicated in patients who are unable or unwilling to be treated with heparin or an appropriate alternative anticoagulation. Although right ventricular heart failure is infrequent, it may occur following cardiac surgery, myocardial infarction (MI), heart transplantation, or implantation of an LVAD. The device is intended to keep the patient alive until the heart recovers, the patient undergoes a heart transplant, or a long term VAD is implanted. The CentriMag is a continuous flow, centrifugal-type rotary blood pump. It is unique in that it is designed to operate without mechanical bearings or seals. This is possible because the motor levitates the rotor (i.e., the spinning component of the device) magnetically.

According to the FDA Summary of Safety and Probable Benefit, data from two unpublished U.S. pilot trials were considered in the HDE approval process. The Cardiogenic Shock Pilot trial (n=22) was a non-randomized multicenter pilot study to evaluate the CentriMag system for up to 14 days when used as either an LVAS or biventricular assist system (BVAS) to treat patients in cardiogenic shock. Two groups were evaluated: patients in cardiogenic shock following cardiomyopathy, and patients in cardiogenic shock following MI. Eight of the 22 patients were treated with a CentriMag for left-sided support only, and 14 patients were treated with a CentriMag RVAD as part of a biventricular configuration, with a CentriMag device also serving as an LVAD. The RVAS Post-Commercial LVAD trial (n=10) was a nonrandomized, multicenter pilot trial to evaluate the use of the CentriMag System for up to 14 days as an RVAS following implantation of a commercially available LVAD. In both studies, success was defined as survival for 30 days after weaning, transplant, or being placed on a long-term VAD. The 30-day survival rate in the 24 patients who received RVAD support was 50%. The survival rate in the RVAS cohort treated solely for right-sided support was 60%. According to the FDA summary, the probable benefits of the CentriMag RVAS include adequate ventricular unloading, adequate circulatory support, ease of implantation, reliable device function, a low incidence of device-related complications, and support conditions conducive to postoperative recovery and weaning. The summary states that the positive outcome data combined with the low incidence of device related adverse events suggest the benefits associated with the use of the CentriMag RVAS VAD outweigh the risks.

The DeBakey VAD[®] Child

The DeBakey VAD Child (MicroMed Technology, Inc.) received FDA Humanitarian Device Exemption (HDE) approval on June 10, 2003. The DeBakey VAD HDE approval was based on a review of data from 190 adults

who were implanted with the DeBakey VAD. According to the FDA Summary of Safety and Probable Benefit, the DeBakey VAD Child is expected to provide the same benefits for children that the adult version has provided for adults, with flow rates that will meet the level of output required to support pediatric patients. The HDE approval was also based on extensive mechanical testing performed by the manufacturer. The data showed that the miniaturized device has a reasonable probability of being safe and effective in children. The FDA Summary of Safety and Probable Benefit states that the DeBakey VAD Child is indicated to provide temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients who meet all of the following criteria:

- age 5–16
- body surface area (BSA) $\geq 0.7 \text{ m}^2$ and $< 1.5 \text{ m}^2$
- in NYHA Class IV end-stage heart failure
- refractory to medical therapy
- listed candidate for cardiac transplantation

The following contraindications are listed in the FDA Instructions for Use:

- patients under age five or with BSA $< 0.7 \text{ m}^2$
- patients suffering from right ventricular failure unresolved by medical therapy
- patients with a primary coagulopathy or platelet disorders
- prior surgery where apical cannulation, pump replacement or graft anastomosis is not feasible

Percutaneous Ventricular Assist Devices

TandemHeart® PTVA® System (CardiacAssist, Inc., Pittsburgh, PA): The TandemHeart PTVA System consists of three components. The TandemHeart Transseptal Cannula Set-EF received FDA approval through the 510(k) process on January 17, 2006. The TandemHeart® Escort™ Controller received FDA approval through the 510(k) process on August 22, 2006. The Controller is a reusable, microprocessor-based pump motor drive and infusion system. The controller and cannula set are used with the TandemHeart PTVA Blood Pump. The controller generates the signals required to power the drive motor of the blood pump, which turns the impeller to propel blood through the pump.

According to the FDA 510(k) summary, the TandemHeart PTVA System is intended for extracorporeal circulatory support using an extracorporeal bypass circuit. The intended duration of use is for periods appropriate to cardiopulmonary bypass, up to six hours. It is also intended to be used as an extracorporeal circulatory support system (for periods up to six hours) for procedures not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, mitral valve reoperation, surgery of the vena cava and/or aorta, liver transplant).

Impella Recover® LP 2.5 Percutaneous Cardiac Support System (Abiomed, Inc., Danvers, MA): The Impella Recover LP 2.5 Percutaneous Cardiac Support System received FDA 510(k) approval on May 30, 2008. The system provides circulatory support with the ability to deliver anticoagulant through an infusion system. It consists of a catheter which contains an integrated pump motor/infusate lumen; integrated intravascular pressure lumen and integral cannula; a controller/console; infusion system; and accessories. These components are designed to work together. The Impella Recover is intended for partial circulatory support using an extracorporeal bypass control unit for periods up to six hours. It is also intended to be used to provide partial circulatory support (for periods up to six hours) during procedures not requiring cardiopulmonary bypass.

The Impella 5.0 Catheters received FDA approval through the 510(k) process on April 16, 2009. The Impella 5.0 catheter family is an extension of the Impella Percutaneous Cardiac Support line. There are two versions of Impella 5.0; the Impella 5.0 LP is inserted through the femoral artery via cutdown, and the Impella 5.0 LD is inserted through the aorta. The only difference between the two catheters is the shape of the inflow cannula. The characteristics of the Impella 5.0 are similar to the Impella 2.5, but the larger pump in the Impella 5.0 permits a higher flow range, up to 5 liters per minute.

Literature Review: VADs

Bridge to Recovery: VADs have been used since the 1970s as a bridge to recovery for patients with potentially reversible left ventricular dysfunction. Patients who undergo cardiac surgical procedures are at risk

for myocardial injury because of myocardial stunning and ischemia, insufficient myocardial protection, reperfusion injury, and cardiac arrhythmias. Patients who have had persistent or significant dysfunction prior to the surgery are less likely to be weaned from device support, while those who had sufficient myocardial reserve prior to surgery may only require a few days of temporary support. In general, patients in profound shock with end-organ dysfunction and biventricular heart failure need early, effective support to avoid permanent end-organ damage and increase their chances of survival. Devices that provide full ventricular support can reestablish nearly normal hemodynamics, and have the potential to allow myocardial recovery. If prolonged support is anticipated, a longer term biventricular device may be implanted, or a longer term LVAD may be used in conjunction with a short-term RVAD device.

VADs have also been shown to be effective as a bridge to recovery in patients with acute myocarditis, particularly in young patients. It is difficult to determine which patients will recover after short-term support and which patients will need long-term device therapy. For this reason a long-term device may be inserted, and the device can be explanted if hemodynamic recovery is sufficient, or left in place as a bridge to transplantation.

Bridge to Transplantation: A number of published studies have evaluated LVADs as a bridge to transplantation. Frazier et al. (2001) conducted a prospective, multicenter, nonrandomized, controlled study (n=280) to evaluate LVAD as a bridge to transplantation. A total of 280 transplant candidates at 24 centers were treated with the HeartMate LVAD and compared to a historical control group of 48 patients not supported with LVADs. Outcome measures were defined as laboratory data (hemodynamic, hematologic and biochemical), New York Heart Association (NYHA) functional class, and survival. The mean duration of support was 112 days, with 54 patients supported for more than 180 days. A total of 188 patients (67%) were bridged to transplantation, and 10 patients (4%) elected to have the device removed. Of the LVAD patients, 82 patients (29%) died before transplantation, compared to 32 patients (67%) of the 48 control patients. Complications included bleeding, infection, neurological dysfunction and thromboembolic events. One-year post-transplant survival was significantly higher in patients in the LVAD group than in those in the control group: 158 patients (84%) vs. 10 patients (63%), respectively.

A prospective, multicenter nonrandomized trial (n=39) evaluated the Thoratec IVAD as a bridge to transplant (n=30) or for patients in post-cardiotomy recovery who could not be weaned from cardiopulmonary bypass (n=9) (Slaughter, et al., for the IVAD Study Group, 2007). The paracorporeal version of this VAD received FDA approval in 1995 as a bridge to transplantation and in 1998 for post-cardiotomy recovery. The implantable version received FDA approval in 2004. This study compared the results of the clinical trial on which FDA approval of the IVAD was based, to a historical control group of patients who received the peripheral VAD. A total of 28 male and 11 female patients with a mean age of 48 and mean BSA of 1.9 m² were supported for 3938 patient-days (10.8 patient years). Twenty four patients received LVADs and 15 received biventricular assist devices. The control group consisted of 100 patients from the FDA approval submission for the paracorporeal version of the VAD. Eighteen patients were discharged after a mean hospitalization of 96 days. There were no device failures. Complications included bleeding that required re-exploration in 13 patients (33.3%), one embolic and two hemorrhagic strokes (7.7%), five driveline infections (12.8%), and two pocket infections (5%). The IVAD provided support to a successful outcome in 70% of bridge to transplant patients and 69% of post-cardiotomy patients, compared to historical results for the paracorporeal device of 69% for bridge to transplant and 48% for post-cardiotomy recovery. The authors stated that the results of this study establish the Thoratec IVAD as an option for patients with end-stage heart failure. Although patients with peripheral VADs may be discharged with the device, an implantable VAD may facilitate hospital discharge, improve postoperative management, and help patients with psychosocial issues and acceptance of the device.

Maybaum et al., for the LVAD Working Group (2007) conducted a prospective, multicenter observational study to evaluate the incidence of myocardial recovery in patients bridged to transplantation with LVAD support. Heart failure patients treated with LVAD implantation as a bridge to transplantation between August 2001 and October 2003, with at least 30 days of device support, were eligible for the study. Patients were evaluated following LVAD insertion by rest echocardiograms with partial LVAD support, and by cardiopulmonary exercise testing. Dobutamine echocardiography with hemodynamic measurements was performed in patients with an ejection fraction > 40% during resting studies. At 30 days, significant improvement in LVEF was seen following VAD insertion, compared to pre-VAD measures (17± 7% vs. 34 ± 12%, p<0.001). Reductions in LV end-diastolic diameter (7.1±1.2 vs. 5.1±1.1 cm; p<0.001), and left ventricular mass (320±113 vs. 194±79 grams; p<0.001) were also observed following LVAD insertion. LVEF improved significantly in almost all patients, but extended LVAD support appeared to have a negative impact on LV function. LVEF decreased over time to pre-LVAD

measurements by 120 days. Tissue analysis demonstrated significant reductions in myocyte size, collagen content, and cardiac tumor necrosis factor. Functional capacity improved throughout LVAD support despite a lack of change in peak LVAD flow or LVEF, suggesting peripheral factors may account for much of the long-term improvement. Although cellular recovery and significant improvements in ventricular function occurred, the degree of clinical recovery did not allow device explantation in most patients. Full recovery with LVAD explantation was rare, occurring in only 9% of patients. The majority of these patients had acute presentations and nonischemic heart failure origins.

Pagani et al., for the HeartMate II Investigators (2009) conducted a prospective multi-site case series evaluating the use of the HeartMate II LVAD as a bridge to transplantation (n=281). Patients were required to have symptoms of NYHA functional class IV heart failure and be ill enough to have high priority for transplant. At 18 months, 222 patients (79%) received a transplant, 58 (20.6%) remained alive with ongoing LVAD support, 56 (19.9%) died, 7 (2.5%) recovered cardiac function, and 3 (1%) were withdrawn from the study and received another type of LVAD. There were significant improvements in functional status and six-minute walk test at three six months (from 0 to 83% of patients in NYHA Class I or II, and from 13% to 89% of patients completing the six-minute walk test). Significant improvements were also seen in quality of life as measured by the Minnesota Living with Heart Failure and Kansas City Cardiomyopathy questionnaires. Major adverse events included bleeding, stroke, right heart failure, percutaneous lead infection, and pump thrombosis.

Bridge to Transplantation in Children

Extracorporeal membrane oxygenation support (ECMO) has been routinely used in pediatric patients awaiting heart transplantation, but this treatment is limited to the inpatient setting. Waiting times for allografts frequently exceed the period of time a patient can be supported on ECMO. The use of long-term mechanical circulatory support has therefore increased over the past ten years as a bridge to transplantation for pediatric patients (Blume et al., 2006).

Blume et al. (2006) conducted a retrospective study to describe the clinical course and adverse events in 99 pediatric patients who underwent VAD implant as a bridge to heart transplantation, to define risk factors for death while waiting on support, and to compare post-transplantation survival between patients who did and did not receive a VAD. Data were analyzed from the Pediatric Heart Transplant Study database for the period of January 1993–December 2003. The database is a prospectively maintained database of patients younger than age 18 who are listed for heart transplantation at 23 North American centers. Four percent (n=99) of 2375 enrolled patients underwent VAD implantation prior to transplantation. Various VADs and combinations of VADs were used. None of these were pediatric-specific devices. The median age at VAD implantation was 13.3 years (range two days–17.9 years). The diagnosis was cardiomyopathy in 78% of patients, and congenital heart disease in 22% of patients. The mean duration of support was 57 days (range, 1–465 days). Seventy seven patients (77%) survived to transplantation, five patients were successfully weaned from support, and 17 patients (17%) died on support. The probability of successful bridge to transplantation was 85%, 80%, and 76% at one, three and six months, respectively. Risk factors for death while awaiting transplantation included earlier era of implantation (p=0.05), female gender (p=0.02), and congenital disease diagnosis (p=0.05). Evaluation of data from the more recent period of 2000–2003 demonstrated a success rate of 86% for the use of VAD as a bridge to transplantation. There were 17 deaths after VAD implantation due to stroke (11), infection/sepsis (3), multi-system organ failure (2), and dysrhythmia (1). There was no difference in five-year survival after transplantation for the 99 patients on VAD at the time of transplant compared to the 2293 who did not require VAD (77% vs. 73%, p=0.8).

Although most studies are nonrandomized and many are retrospective, there is sufficient evidence that LVADs can improve functional and hemodynamic status and are associated with higher survival rates when compared to optimal medical therapy. In addition, improved post-transplant survival rates are seen in patients who received LVADs. This benefit of improved post-transplant survival is likely due to the efficient circulatory support provided by the device, as well as the fact that patients stabilized by LVAD implantation can wait for an optimal organ match. LVADs have therefore become an accepted tool to halt further deterioration, decrease the likelihood of death before transplantation, and improve long-term survival and quality of life in selected patients.

Destination Therapy: The REMATCH trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart failure) was a multicenter, randomized controlled trial comparing LVADs with medication (Rose, et al., 2001). Patients with chronic end-stage heart failure and contraindications to transplant (n=129) were randomly assigned in a 1:1 ratio to receive either an LVAD (n=68) or optimal medical therapy

(n=61). The surgical risk associated with implantation of the device and the obviousness of the device precluded a double-blind study design. The risk of death by any cause was reduced by 48% in the LVAD group as compared to the medical therapy group. The rates of survival at one year were 52% in the LVAD group and 25% in the medical therapy group, and rates at two years were 34% and 8%, respectively. The frequency of serious adverse events in the LVAD group was 2.35 times that of the medical therapy group. Infection, bleeding, and malfunction of the device were the most frequent adverse events. Quality of life, as measured by physical-function and emotional-role subscales of the SF- (Standard Form) 36, was significantly improved at one year for the LVAD group.

Park et al. (2005) conducted a follow-up analysis of extended survival and adverse events of patients in the REMATCH trial. During the enrollment period of the REMATCH trial (1998–2001), the clinical management of patients receiving LVADs evolved, and device modifications were introduced. This study also explored how these changes may have affected patient outcomes. As of July 2003, 11 patients were alive on LVADs out of a total 16 survivors, including three patients who had been receiving optimal medical management who crossed over to LVAD therapy. There was a significant improvement in the survival of patients receiving LVADs during the second half of the trial compared with the first half. In addition, the Minnesota Living with Heart Failure scores improved significantly over the course of the trial. The researchers concluded that this trial confirmed initial observations that LVAD therapy provides significant survival and quality of life benefits and that the effect of greater clinical experience with LVADs resulted in improved survival.

Lietz et al. (2007) analyzed outcomes of destination therapy in 280 advanced heart failure patients who underwent LVAD implantation after the completion of the REMATCH trial and subsequent FDA approval of the modified HeartMate XVE LVAD as destination therapy. The study was designed to determine the impact of the HeartMate XVE LVAD as destination therapy and to identify preoperative predictors of in-hospital mortality after implantation. A preoperative risk score for in-hospital mortality was established for 222 patients with complete data. All patients were followed until death or until December 2006. In-hospital mortality following LVAD implantation was 27%. Causes of death included sepsis, right heart failure, and multi-organ failure. Poor nutrition, hematological abnormalities, markers of end-organ or right ventricular dysfunction, and lack of inotropic support were the primary determinants of in-hospital mortality. Stratification of destination therapy candidates into low (n=65), medium (n=111), high (n=28) and very high (n=18) risk on the basis of the risk score calculated from these predictors corresponded with one-year survival rates of 81%, 62%, 28%, and 11%, respectively. The authors stated that patients with advanced heart failure who are referred for destination therapy before major complications develop have the best changes of achieving one-year survival with LVAD therapy.

Slaughter et al., for the HeartMate II Investigators (2009) conducted a randomized controlled trial to evaluate the use of a continuous flow device vs. a pulsatile device in patients with advanced heart failure who were ineligible for transplantation. Enrolled patients met the following criteria: a left ventricular ejection fraction of less than 25%; a peak oxygen consumption of less than 14 ml per kilogram of body weight per minute, or less than 50% of the predicted value; and New York Heart Association (NYHA) class IIIB or IV symptoms for at least 45 of the 60 days before enrollment, or dependence on an intra-aortic balloon pump for a period of 7 days or inotropes for a period of at least 14 days before enrollment. Patients were randomized on a 2:1 basis to undergo implantation of a continuous flow device (HeartMate II; n=134) or a pulsatile flow device (HeartMate XVE; n=66). The primary composite end point was survival free from disabling stroke and reoperation to repair or replace the device at two years. Secondary end points included survival, frequency of adverse events, quality of life, and functional capacity. The primary composite end point was achieved at two years in more patients with the continuous flow devices than with the pulsatile flow devices (62 of 134 [46%] vs. 7 of 66 [11%]; $p < 0.001$). Patients with the continuous flow devices had superior survival rates at two years (58% vs. 24%, $p=0.008$). Adverse events and device replacements were less frequent with continuous flow devices. Quality of life and functional capacity improved significantly in both groups.

Rogers et al. for the HeartMate II Investigators (2010) evaluated the impact of a continuous flow LVAD on functional capacity and heart failure-related quality of life. Data from advanced heart failure patients enrolled in the HeartMate II LVAD bridge to transplantation (BTT) (n=281) and destination therapy (DT) (n=374) trials. The authors assessed functional status as measured by NYHA functional class, six-minute walk distance, patient activity scores), and quality of life, as measured by the Minnesota Living With Heart Failure (MLWHF) and Kansas City Cardiomyopathy Questionnaires (KCCQ), prior to and after LVAD implantation. Patients demonstrated early and sustained improvements in functional status and quality of life compared to baseline.

Most patients had NYHA functional class IV symptoms at baseline. Following implantation, 82% of bridge-to-transplant (BTT) patients and 80% of destination therapy (DT) patients improved to NYHA functional class I or II at six months. At 24 months, 79% of DT patients improved to NYHA functional class I or II at 24 months. The mean six-minute walk test in DT patients was 204 m in patients able to ambulate at baseline, improving to 350 and 360 m at 6 and 24 months, respectively. There were also significant and sustained improvements in BTT and DT patients in median MLWHF scores and KCCQ overall summary scores at 6 and 24 months.

There is adequate evidence in the published medical literature that LVAD therapy is effective as destination therapy for selected end-stage heart failure patients who are not eligible for heart transplantation. A Centers for Medicare & Medicaid (CMS) proposed coverage decision memorandum for VADs as destination therapy was issued on August 19, 2010. The proposed decision memo discusses the HeartMate II pivotal trial by Slaughter et al. and the Rogers et al. trial (discussed above), and other published evidence, reviews, and guidelines. The memo proposes coverage for patients with NYHA Class IV end-stage ventricular heart failure who are not candidates for heart transplant and who meet all of the following conditions:

- failed to respond to optimal medical management (including beta blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been a balloon pump dependent for 7 days, or IV inotrope dependent for 14 days
- LVEF < 25%
- have demonstrated functional limitations with peak oxygen consumption of 14 ml/kg/min

The proposed coverage is aligned with the entry criteria for the Slaughter trial, but limits coverage to NYHA Class IV patients. Comments on the proposed NCD submitted by the American College of Cardiology (ACC) and The Society of Thoracic Surgeons (STS) support CMS proposal not to extend coverage for VADs as destination therapy for NYHA class IIIB heart failure patients. The ACC/STS letter states, "Trial data does not provide any basis of evidence for mechanical circulatory support for Class III patients. The vague characterization of Class III has yet to be crystallized into clinical phenotypes as has begun for Class IV. There is no validated division into Class IIIA, IIIB, and most heart failure physicians would have difficulty finding a reference for this specific classification or to define the specifics of this population."

VAD components vary, depending on the device and where it is to be used (inpatient vs. outpatient). In addition to the implanted device, components may include a system controller, system monitor, display module, power base, emergency power pack, power pack charger, rechargeable batteries, cannulae, and cables. The treating physician should contact CIGNA to discuss the need for associated equipment and supplies if discharge with an LVAD is being considered.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom)

In June 2006, NICE issued Interventional Procedure Guidance on short-term circulatory support with LVADs. The guidance states that limited evidence on the safety and efficacy of short-term circulatory support with LVADs as a bridge to cardiac transplantation or recovery appears adequate to support the use of this procedure, provided that the normal arrangements are in place for audit and clinical governance.

The published guidance states that management of patients with end-stage heart failure or acute heart failure from naturally reversible causes is challenging and may involve combination medical therapy (including inotropic support), intra-aortic balloon pumping and heart transplantation. Short-term circulatory support with an LVAD may be indicated for patients with end-stage heart failure of any etiology who are awaiting a donor heart for transplantation, and for patients with a severe acute heart failure syndrome from which myocardial recovery is anticipated (e.g., acute myocarditis). An LVAD is also sometimes used if weaning from cardiopulmonary bypass after cardiac surgery fails.

Literature Review: Percutaneous Ventricular Assist Devices (VADs)

Thiele, et al. (2005) conducted a randomized controlled trial to evaluate hemodynamic effects of the intra-aortic balloon pump (IABP) compared to the TandemHeart, and to assess mortality in patients with cardiogenic shock complicating acute myocardial infarction (MI). Patients were randomized to treatment with the IABP (n=20) or TandemHeart (n=21). Inclusion criteria were the presence of acute MI and cardiogenic shock with an intention to revascularize the infarcted artery by percutaneous coronary intervention (PCI). Hemodynamic indices at baseline were similar for both groups, except for a higher pulmonary capillary wedge pressure in the IABP group. The primary endpoint, cardiac power index, was improved more effectively with the TandemHeart,

($p < 0.001$) compared to the IABP ($p = 0.02$) ($p = 0.004$ for intergroup comparison). Weaning from the devices was completed using a stepwise approach over a period of four to eight hours. Complications occurred more frequently in the TandemHeart group compared to the IABP group, however. Severe bleeding occurred in 19 TandemHeart patients compared to 8 IABP patients ($p = 0.002$), and limb ischemia occurred in 7 TandemHeart patients compared to 0 IABP patients. Thirty-day mortality was similar in both groups (IABP 45% vs. TandemHeart 43%, $p = 0.86$). Although this trial did not have the power to detect differences in mortality, there was no trend in mortality benefit for the TandemHeart patients despite the improved hemodynamics.

Burkhoff et al. (2006) conducted a randomized controlled trial to determine whether the TandemHeart provided superior hemodynamic support compared to IABP in patients with cardiogenic shock ($n = 42$). Patients from 12 centers presenting within 24 hours of developing cardiogenic shock were treated in an initial roll-in phase ($n = 9$), or randomized to treatment with IABP ($n = 14$) or TandemHeart ($n = 19$). Of the 42 patients, 26 were diagnosed with acute MI. Most of the patients had an IABP in place before randomization. The mean duration of support was 2.5 days. Patients treated with the TandemHeart had significantly greater increases in cardiac index and greater decreases in pulmonary capillary wedge pressure compared to those treated with IABP. There was no significant difference in 30-day overall survival or incidence of adverse events between the two groups; serious adverse events occurred with a frequency of 1.3 per patient in the TandemHeart group and 1.2 per patient in the IABP group. The authors noted that larger scale studies are needed to assess the influence of improved hemodynamics on survival.

A randomized controlled trial by Seyfarth et al. (2008) was conducted to determine whether the Impella 2.5 percutaneous VAD provided superior hemodynamic support compared to the IABP ($n = 26$). After an initial hemodynamic assessment, patients with acute MI and cardiogenic shock were randomized to Impella 2.5 ($n = 12$) or IABP ($n = 13$). One patient died prior to implantation. Patients were immediately transferred to the catheterization lab, and the assigned device was implanted after revascularization therapy. The primary endpoint was the change in cardiac index from baseline to thirty minutes after implantation. The cardiac index of patients in the Impella group was significantly increased after thirty minutes of support compared to the IABP group ($p = 0.02$). The median duration of support was 25 hours in the Impella group and 23 hours in the IABP group. There was one case of acute limb ischemia in the Impella group. Transient hemolysis was significantly higher in the Impella group, with more packed red blood cells and fresh frozen plasma administered ($p = 0.18$ and $p = 0.39$, respectively). Overall thirty-day mortality was 46% in both groups.

The Europella Registry (Sjauw et al., 2009) evaluated the safety and feasibility of left ventricular support with the Impella 2.5 during high-risk PCI ($n = 144$). Patients were older (62% > 70), and 54% had a left ventricular ejection fraction (LVEF) $\leq 30\%$. PCI was considered high risk due to left main disease, last remaining vessel disease, multivessel coronary artery disease, and low LV function in 53%, 17%, 81%, and 35% of cases, respectively. Rates of MI, stroke, bleeding requiring transfusion/surgery, and vascular complications at thirty days were 0%, 0.7%, 6.2%, and 4.0%, respectively. Thirty-day mortality was 5.5%.

A multicenter prospective case series conducted by Dixon et al. (2009) evaluated the safety and feasibility of the Impella 2.5 system in patients undergoing high-risk PCI ($n = 20$). All patients had LVEF $\leq 35\%$ and underwent PCI on an unprotected left main coronary artery or last patent coronary conduit. The primary safety end point was the incidence of major adverse cardiac events (MACE) at thirty days. The primary efficacy end point was freedom from hemodynamic compromise during PCI (defined as a decrease in mean arterial pressure below 60 mm Hg for more than ten minutes). The mean duration of support was 1.7 ± 0.6 hours (range 0.4–2.5 hours). The incidence of MACE at thirty days was 20%; two patients had a peri-procedural MI, and two died at days 12 and 14. The authors stated that, based on the results of this trial, a pivotal randomized trial is planned to compare the efficacy of prophylactic circulatory support during high-risk PCI with the Impella 2.5 vs. conventional IABP counterpulsation.

Cheng et al. (2009) conducted a meta-analysis of controlled trials to evaluate potential benefits of percutaneous LVADs on hemodynamics and thirty-day survival. Three trials met the inclusion criteria. Two of these evaluated the TandemHeart (Thiele et al. 2005; Burkhoff et al. 2006) and the third trial evaluated the Impella (Seyfarth et al. 2008). These trials are described above. Weighted mean differences were calculated for cardiac index (CI), mean arterial pressure (MAP), and pulmonary capillary wedge pressure (PCWP). Relative risks were calculated for thirty-day mortality, leg ischemia, bleeding, and sepsis. After implantation, percutaneous LVAD patients had higher CI, higher MAP, and lower PCWP, compared with IABP patients. Similar thirty-day mortality was observed in both groups. No significant difference was seen in incidence of leg ischemia. Bleeding was

significantly higher in TandemHeart patients compared to IABP patients. The authors stated that although percutaneous VADs provide superior hemodynamic support in patients with cardiogenic shock compared with IABP, the use of these devices did not improve early survival, and these results do not yet support percutaneous LVAD as a first-choice approach in the mechanical management of cardiogenic shock.

An ECRI Evidence Report (2010), Miniature Intracardiac Pump for Heart Failure, evaluated the Impella when used as a bridge to recovery in patients at high risk of heart failure during or after PCI, or as a bridge to decision after cardiogenic shock from acute MI. The report considered evidence from two studies that compared the Impella to the IABP (Seyfarth et al., 2008; Sjauw et al., 2008) and nine single-group studies that included 308 patients. The report concluded that too few data are available to determine whether the use of the Impella reduces the time spent on support or reduces the length of hospitalization compared to an IABP. There is also insufficient data to determine whether the use of the Impella for cardiogenic shock or high-risk PCI decreases adverse events or increases survival compared to the IABP. The report concluded that the clinical utility of the intracardiac mini-pump and claims for its purported advantages during PCI cannot be established without comparison of the IABP in a randomized controlled trial.

Ongoing trials evaluating the Impella include PROTECT II (n=654), designed to compare adverse event rates of the Impella 2.5 and IABP in high risk patients undergoing elective PCI, and RECOVER II (n=384), evaluating adverse event rates of the Impella 2.5 compared to the IABP. Evidence from these and other ongoing trials may provide the evidence needed to determine the role of this emerging technology in high risk PCI and in the treatment of cardiogenic shock.

VADs Under Development: Several additional VADs are currently being evaluated in clinical trials but have not received FDA approval, including the following:

- DuraHeart™ Left Ventricular Assist System (Terumo Heart, Inc., Ann Arbor, MI)
- EXCOR® Pediatric Ventricular Assist Device (Berlin Heart, Inc., The Woodlands, TX)
- HeartWare® Left Ventricular Assist System (HVAD™) (HeartWare, Inc., Framingham, MA)
- Jarvik 2000 Flowmaker® (Jarvik Heart, Inc., New York, NY)
- Levacor Ventricular Assist Device® (World Heart Corporation, Salt Lake City, UT)

Professional Societies/Organizations

The American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for the Management of ST-Elevation Myocardial Infarction (Antman et al., 2004) does not include mention of percutaneous VADs. The guideline provides several recommendations for IABP use for indications comparable to those for which percutaneous VADs have been proposed. Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk ≥ Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

Recommendations for IABP use in the ST elevated MI (STEMI) guideline include the following:

Class I:

- Intra-aortic balloon counterpulsation is recommended for STEMI patients when cardiogenic shock is not quickly reversed with pharmacological therapy. The IABP is a stabilizing measure for angiography and prompt revascularization (Level of evidence: B)
- Intra-aortic balloon counterpulsation should be used in STEMI patients with hypotension (systolic blood pressure less than 90 mm Hg or 30 mm Hg below baseline mean arterial pressure) who do not respond to other interventions, unless further support is futile because of the patients wishes or contraindications/unsuitability for further invasive care (Level of evidence: B)
- Intra-aortic balloon counterpulsation is recommended for STEMI patients with low-output state (Level of Evidence: B)
- Intra-aortic balloon counterpulsation is recommended for STEMI patients when cardiogenic shock is not quickly reversed with pharmacological therapy. IABP is a stabilizing measure for angiography and prompt revascularization (Level of evidence: B)
- Intra-aortic balloon counterpulsation should be used in addition to medical therapy for STEMI patients with recurrent ischemic-type chest discomfort and signs of hemodynamic instability, poor LV function, or a large area of myocardium at risk. Such patients should be referred urgently for cardiac catheterization and should undergo revascularization as needed (Level of evidence: C)

A 2009 focused update of the STEMI guideline (Kushner et al.) does not include mention of percutaneous VADs.

The American College of Cardiology/American Heart Association (ACC/AHA) 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult (Hunt, et al., 2009) states that the use of mechanical circulatory assist devices in end-stage heart failure is an area of intense investigation. Extracorporeal devices can be used for short-term circulatory support in patients who are expected to recover from a major cardiac insult (e.g., myocardial ischemia, postcardiotomy shock, or fulminant myocarditis). LVADs provide similar levels of hemodynamic support. Many are implantable, and thus allow for long-term support, patient ambulation and hospital discharge. The guideline states that while most clinical experience with the devices has been derived from use as a bridge to transplantation, the REMATCH trial established the efficacy of device therapy for end-stage heart failure. The authors stated that presently, destination therapy is anticipated to benefit those patients predicted to have a one-year survival of less than 50%, but improvements in newer generations of devices may permit even further prolongation of survival.

The following is included in the guideline recommendations for the treatment of patients with refractory end-stage heart failure (stage D):

Class IIa:

Consideration of an LV assist device as permanent or “destination” therapy is reasonable in highly selected patients with refractory end-stage HF and an estimated 1-year mortality over 50% with medical therapy. (Level of evidence: B)

The ACC/AHA/SCAI (Society for Cardiac Angiography and Interventions) 2005 Guideline Update for Percutaneous Coronary Intervention (Smith et al., 2005) does not mention percutaneous VADs and does not include specific guideline recommendations for IABP use. In discussing high-risk PCI, the authors state, “Available data for the use of IABP in high-risk patients involve retrospective analyses of relatively small numbers of patients; therefore, no formal recommendations are suggested. The decision to proceed with IABP before PCI remains a clinical judgment made by the physician based on the high-risk characteristics of coronary anatomy and overall status of the patient.” Percutaneous VADs are not mentioned in a 2007 guideline update for PCI (King et al.).

A comprehensive heart failure practice guideline (Adams, et al., 2006) published by the Heart Failure Society of America (HFSA) states that 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. The HFSA guideline also states that permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe 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 heart failure center. The guideline process uses three grades, A, B, and C, to characterize the type of evidence available to support specific recommendations. Both of the above

recommendations are based on strength of evidence B, indicating that the evidence consists of cohort and case-control studies.

Summary

There is adequate evidence in the published medical literature to demonstrate that ventricular assist devices (VADs) can be effective when used on a short-term basis in the acute care setting as a bridge to recovery for patients in acute cardiogenic shock or acute myocarditis and for patients following cardiac surgery who cannot be weaned from cardiopulmonary bypass. There is also adequate evidence that VADs improve hemodynamic and functional status when used as a bridge to cardiac transplantation, and as destination therapy in selected patients who are not candidates for transplantation. Although VADs are associated with significant risks and complications, they are responsible for improved pre- and post-transplant survival rates and improved quality of life. For all indications, patients must, at a minimum, meet the United States Food and Drug Administration (FDA)-defined, device-specific inclusion and exclusion criteria.

Percutaneous VADs, including the TandemHeart and Impella, have been proposed as an alternative to a traditional VAD or intra-aortic balloon pump (IABP) for short-term partial or total hemodynamic support. Unlike traditional VADs used for short-term support, percutaneous VADs are minimally invasive and do not require surgical implantation, and unlike IABP, percutaneous VADs provide hemodynamic support independent of left ventricular function. There is insufficient evidence in the published medical literature, however, to demonstrate the safety and efficacy of these devices, or to determine how the use of this emerging technology impacts outcomes. Outcomes of ongoing trials may provide the evidence needed to determine the role of percutaneous VADs in high risk PCI and in the treatment of cardiogenic shock.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

Note: The codes listed below are not covered when used to report services associated with percutaneous ventricular assist devices (VADs) or any other services determined to be not covered as outlined in this Coverage Policy.

CPT ^{®*} Codes	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33977	Removal of ventricular assist device; extracorporeal, single ventricle
33978	Removal of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable, intracorporeal, single ventricle
33980	Removal of ventricular assist device, implantable, intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump (Code effective 1/1/10)
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass (Code effective 1/1/10)
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass (Code effective 1/1/10)
33999 [†]	Unlisted procedure, cardiac surgery
0048T	Implantation of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation
0050T	Removal of a ventricular assist device, extracorporeal, percutaneous transseptal access, single or dual cannulation

† Covered when used to report the replacement of a ventricular assist device, extracorporeal, percutaneous access.

HCPCS Codes	Description
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type (code effective 01/01/2011)
Q0479	Power module for use with electric or electric/pneumatic ventricular assist device, replacement only (code effective 01/01/2011)
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
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 pack 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, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
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/bag for use to carry external peripheral components of any type 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
Q0505	Miscellaneous supply or accessory for use with ventricular assist device
Q0606	Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only (code effective 01/01/2010)

ICD-9-CM Diagnosis Codes	Description
410.00-410.92	Acute myocardial infarction
422.0	Acute myocarditis in diseases classified elsewhere
422.90	Acute myocarditis, unspecified
422.91	Idiopathic myocarditis
422.92	Septic myocarditis
425.4	Other primary cardiomyopathies
425.9	Secondary cardiomyopathy, unspecified
428.0	Congestive heart failure, unspecified
428.40	Combined systolic and diastolic heart failure, unspecified
428.1	Left heart failure
428.41	Combined systolic and diastolic heart failure, acute
428.42	Combined systolic and diastolic heart failure, chronic
428.43	Combined systolic and diastolic heart failure, acute or chronic
428.9	Heart failure, unspecified
429.4	Functional disturbances following cardiac surgery
785.51	Cardiogenic shock

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Procedure Codes	Description
37.68	Insertion of percutaneous external heart assist device

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	05/15/208	0054	Ventricular Assist Devices (VADs)

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.