

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Patient Referral Guidelines for Use of Mechanical Circulatory Support Devices as a Bridge to Cardiac Transplant

Artificial Hearts

- AbioCor
- SynCardia

Ventricular Assistive Devices

- Implanted Ventricular Assist Devices (VAD)
- Percutaneous Left Ventricular Assist Device (PLVAD)

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Artificial Hearts and Related Devices (20.9)
	Ventricular Assist Devices (20.9.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	11/01/2023 Noridian retired Percutaneous Endovascular
	Cardiac Assist Procedures and Devices (A52967)
	These services still need to meet medical necessity as outlined
	in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the
	·
	material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an
	article. Most LCAs are not retired because they are incorrect.
	Therefore, continue to use LCA A52967 for determining
	medical necessity.

For Non-Medicare Members

OVERVIEW

These guidelines have been developed from the major clinical trials. However, acute changes occur in this group of patients and it is often uncertain which parameters are reversible. It is important to know that these are quidelines and should be applied together with careful clinical judgment.

Devices: The type of device used is dependent upon the implanting center and the device used by the center. Common devices include Heartmate I, II or III, HeartWare and Total Artificial Heart. Non-durable devices include Impella, ECMO, V-A ECMO. These are common devices and *not* an all-inclusive list.

Inclusion Guidelines (one or more should be present to indicate the patient is ill enough to warrant MCS support):

© 2007 Kaiser Foundation Health Plan of Washington. All Rights Reserved.

Back to Top

- 1. NYHA class III-IV symptoms, and/or intractable ventricular arrhythmia, approved by Kaiser Permanente for, and currently listed by UNOS as a candidate for heart transplant, or are being evaluated as a candidate for transplant.
- 2. INTERMACS Profile 1, 2, 3, or 4 (see Appendix 1).
- 3. One or more objective indicators of failing support despite maximum reasonable and tolerated medical therapy may include one or more of the following:
- 3.1. Systemic mean BP < 60mmHg or systolic BP <80 mmHg
- 3.2. Cardiac index < 2.0 L/min/m²
- 3.3. Pulmonary capillary wedge pressure (or PA diastolic) > 20 mmHg
- 3.4. A low VO₂ maximum¹
 - 3.4.1. VO₂ < 12 mL/kg/min on a beta-blocker
 - 3.4.2. VO₂ < 14 mL/kg/min off beta-blockade
 - 3.4.3. VO_2 < 19 mL/kg/min adjusted for lean body mass in patients with a BMI > 30 kg/m.
 - 3.4.4. Less than 50% of age predicted maximum.
- 3.5. A VE/VCO₂ > 35 in a patient with a submaximal cardiopulmonary exercise test (RER <1.05)¹
- 3.6. Inability to wean from other mechanical or inotropic support
- 3.7. Refractory Life-Threatening Arrhythmias

4. Exclusion guidelines include:

- 4.1. Severe renal dysfunction unlikely to be reversible such as creatinine > 3.0 mg/dl (unless patient is listed for combined heart/kidney transplant).
- 4.2. Severe hepatic dysfunction unlikely to be reversible such as bilirubin > 5.0 mg/dl,
- 4.3. Infection as evidenced by ongoing fever (T > 38°C), WBC > 15,000/mm3 or positive blood cultures or specific site of infection (e.g. pneumonia, diverticulitis, pyelonephritis),
- 4.3. Platelet or coagulation disorder likely to compromise survival with the anticoagulation protocol required with the device,
- 4.4. Other conditions which would negate transplant candidacy such as peripheral or cerebral vascular disease, or cancer,
- 4.5. Co-morbidities, which alone may not be considered contraindications to transplantation but, taken together, may make the combination of MCS use and transplantation unreasonable or ill-advised.

5. Special Considerations:

- 5.1. Aortic Valve Disease Patients with mechanical prosthetic aortic valve or uncorrected valvular disease, such as severe aortic insufficiency, will require additional surgical intervention at the time of MCS implant.
- 5.2. Right Ventricular Dysfunction Evidence of right-sided cardiac dysfunction may indicate the need for biventricular support.
- 5.3. Pulmonary hypertension not reversible by drug manipulation (PVR >4-6 Wood units or transpulmonary gradient >15mmHg, despite maximum tolerated medical management) is not a contraindication to MCS implantation. Some patients may experience reversal of pulmonary hypertension with MCS implantation and may then become eligible for cardiac transplantation.

Appendix 1

INTERMACS Profiles:

- 1 = Critical cardiogenic shock
- 2 = Progressive decline on Inotropic support
- 3 = Inotrope dependent but stable
- 4 = Resting symptoms on home oral therapy
- 5 = Exertion intolerant
- 6 = Exertion limited
- 7 = Advanced NYHA class III

REVISED BY CMS: AUGUST 6, 2019

ADVISORY COUNCIL APPROVED EFFECTIVE DATE: OCTOBER 24, 2019

If requesting this service, please send the following documentation to support medical necessity:

Last 2 Cardiology/Cardiovascular Surgery consults

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Artificial Hearts

Congestive heart failure is a major health problem affecting more that five million patients in the United States. There is a wide variety of options for medical management of heart failure, but many patients eventually deteriorate and fail to respond to any of the medical therapies and require mechanical circulatory support for survival. In order to provide long-term systemic flow for patients with end-stage heart failure, the National Heart Institute established the artificial heart program in the mid 1960s with the intent to develop a totally implantable mechanical heart.

The AbioCor (Abiomed Inc, Danvers, MA, USA) is the world's first fully implantable total artificial heart. This was first implanted in 2001 at the Jewish Hospital in Louisville, KY. AbioCor is a pneumatically-driven biventricular cardiac support device designed to last at least 18 months. It is made of titanium and Angioflex, a proprietary polyurethane plastic and can produce a flow of up to 8 L/min, sufficient for moderate activity. It is divided into the implantable components and the external drive system. The implanted components consist of the thoracic unit, controller, Transcutaneous Energy Transmission system, and a battery that provides about 30 minutes of power that is designed to allow patients to conduct activities such as taking a shower without an external power source. The external drive system consists of the AbioCor console and support electronics worn or carried by the patient in a waist belt (providing power for 2-4 hours) and an RF communication system for a computer (Samuels 2003, Meyer 2011).

In September 2006, the FDA granted restricted approval of the AbioCor device through the Humanitarian Use Device (HUD) provision. A HUD is a device that the FDA determines is intended to benefit fewer than 4,000 U.S. patients per year. The FDA approval included an agreement by the manufacturer to conduct a post-marketing study, evaluating the AbioCor device in an additional 25 patients. According to the FDA, the AbioCor artificial heart is indicated for use in patients who have both ventricles failing, have end-stage heart disease, are not transplant candidates, are less than 75 years old, are not treatable by single left ventricular heart assist devices for destination therapy, and are not able to be withdrawn from heart support measures. It should not be used for patients who are eligible for a heart transplant, have only left sided heart failure, cannot be successfully treated for blood clotting disorders, or in those where the device will not fit (FDA webpage accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH), originally developed 30 years ago as the Jarvik TAH and later renamed the CardioWest TAH, continues to be used clinically in over 50 centers within the US and Europe. This is an implantable artificial heart intended to keep hospitalized patients alive while they are waiting for a heart transplant. It is a pulsating bi-ventricular device that is implanted into the chest to replace the patient's left and right ventricles and all four valves of the native heart. The device is sewn to the patient's remaining atria. Hospitalized patients are connected by tubes from the heart through their chest wall to a large power-generating console, which operates and monitors the device. SynCardia was approved by the FDA in 2004 for use only in the © 2007 Kaiser Foundation Health Plan of Washington. All Rights Reserved.

hospital as a "bridge to transplant" for patients waiting for a heart transplant who have both sides of their heart failing (biventricular heart failure), do not respond to other treatments, are at imminent risk of death, and are waiting for a donor heart. The temporary CardioWest™ TAH is should not be used in patients who are not eligible for a heart transplant, do not fit the device, cannot be adequately anticoagulated, or have left sided heart failure only (Meyer 2011, FDA Web page accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH) has not been previously reviewed by MTAC; AbioCor was reviewed by MTAC in 2007 and did not meet its evaluation criteria. The technology is being reviewed due to the coverage of SynCardia temporary CardioWest™ Total Artificial Heart by other health plans as a bridge to heart transplant.

Medical Technology Assessment Committee (MTAC)

AbioCor

04/02/2007: MTAC REVIEW

<u>Evidence Conclusion:</u> There are no published empirical studies on the safety and efficacy of the AbioCor permanent total artificial heart. Unpublished data consists of a feasibility study with 14 patients submitted to the FDA by the device manufacturer. The 12 patients who survived the operation experienced multiple serious adverse effects; only 1 was discharged from the hospital.

<u>Articles:</u> The Medline search yielded 32 articles. These consisted of reviews/commentaries, several empirical studies on technical aspects of the device or device implantation, case reports and 2 case series reporting on 7 patients. The study submitted to the FDA, which included 14 patients, has not been published.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

12/19/2011: MTAC REVIEW

AbioCor

Evidence Conclusion: AbioCor TAH There is no new published evidence after the initial small feasibility study conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. SynCardia temporary CardioWest™ Total Artificial Heart The published evidence on CardioWest TAH consists of a retrospective study, and a few case series of patients receiving the device as a bridge to transplantation. Due to the eligibility criteria for the implantation, it would be unethical to conduct a randomized trial. The only valid control would be no intervention as the eligible patients for the implant are those who failed medical therapy and are not candidates for left ventricular assist device (LVAD). The results of Copeland and colleagues' case series (Evidence table 1) show that 68% of the critically ill patients who received the CardioWest implant survived to heart transplantation and hospital discharge. Adverse events included bleeding in 20% of cases and device malfunction in 5% of cases. Other complications that occurred at a lower rate included mediastinal infection, fit complications, and stroke. The cause of death was multi-organ failure in 50% of the cases, and sepsis or valve entrapment among the rest. A similar experience was observed in a French study among 42 patients. In this series 12 (28.5%) patients died while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively. Causes of death during device support included multi-organ failure (50%), sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. There were no device malfunctions that led to patient death. Adverse events included stroke in 3 patients (7%) and infections in 35 patients (85%) during support.

Articles: The literature search for AbioCor total heart transplant did not reveal any study conducted after the initial small feasibility study (Dawling 2003) conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. The search for SynCardia CardioWest temporary TAH identified a few case series for patients who received the device as a bridge to transplantation, and a retrospective study comparing the device to left ventricular assist devices. The larger case series was selected for critical appraisal. Copeland JG, Smith RG, Arabia FA, et al. Total artificial heart bridge to transplantation: A 9-year experience with 62 patients. *J Heart Lung Transplant* 2004; 23:823-831. See Evidence Table.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

The use of the SynCardia implantable replacement heart in the treatment of irreversible heart failure does meet the Kaiser Permanente Medical Technology Assessment Criteria.

Background

Implanted Ventricular Assist Devices (VAD)

Heart failure is a clinical condition characterized by the heart's inability to generate a cardiac output sufficient to meet the body's circulation demands. It is a major and growing public health problem responsible for high morbidity and mortality, in addition to the economic impact of medical costs, disability, and loss of employment. According to the Heart Failure Society of America, nearly 5 million people suffer from CHF in the United States and it is responsible for about 200,000 deaths each year (Abraham 1998).

The cause of heart failure in many patients is pump failure due to poor left ventricular systolic function, which is often due to myocardial infarction or dilated cardiomyopathy. In approximately 30% of patients with chronic heart failure, the disease process not only depresses cardiac contractility, but also affects the conduction pathways by causing a delay in the onset of right or left ventricular systole, and in turn the loss of coordination of ventricular contraction. This dyssynchronous pattern of ventricular contraction is believed to reduce the already diminished contractile reserve of the heart (Nelson 2001).

Patients in end-stage heart failure have two primary treatment options:

- 1. Pharmacological therapy (including digoxin, ACE inhibitors, diuretics and inotropes), and
- 2. Heart transplantation.

Both treatments have their limitations. Pharmacological therapy is only palliative and improves the short-term survival for patients. Moreover, as the heart failure worsens, medication becomes ineffective in treating the low contractility and pulmonary venous stasis resulting from the increased dilatation of the heart. Cardiac transplantation on the other hand, is limited to the number of available hearts, and the criteria for being a transplant candidate.

In September 1994, the FDA approved the first pneumatically driven left ventricular assist device (LVAD) from TCI for bridging end-stage patients to cardiac transplantation. Patients on these devices had to stay in the hospital connected to a pneumatic console or could go home with extensive home health care support. (FDA News 2002). Four years later, in September 1998, the FDA approved two portable heart assist devices (HeartMate and Novocar LVAS) to support patients outside the hospital while they wait for a transplant. These two devices were approved as a bridge to transplant for patients eligible for heart transplants and waiting for an available heart. Eligible patients were those with irreversible heart failure and a rapidly deteriorating condition. In addition, they had to be on their hospital's transplant list in order to qualify for one of these devices (FDA News, September 1998).

The LVAD does not replace the heart. It works along with the patient's own heart to provide additional strength to the weakened left ventricle to pump blood throughout the body. The portable device consists of a blood pump implanted in the abdominal area and attached to both the left ventricle and the aorta. Blood from the heart flows into the device which then pumps it through the aorta to the rest of the body. The system is also connected by a cable through the skin to a small external computer (the "controller") worn on the waist. The computer can be powered by a base unit that is plugged into the wall or by batteries worn at the waist or, in the case of the HeartMate device, under the arms.

There are risks associated with the surgery to implant the HeartMate, as well as risks and complications with the device itself such as infections, bleeding, thromboembolism, and stroke. Implanting the device requires a major surgery for already seriously sick patients. Moreover, the device requires a percutaneous line that can become a medium for bacterial and fungal infections that are difficult to treat and may require a change of the device, which increases the morbidity and mortality. Another complication reported by Rose et al (2000), is aortic stenosis of variable severity that may be caused by the device. LVAD may also lead to significant changes in the systemic immunologic and thrombostatic functions of the patients (Itesu S, 2000). Failure and malfunctioning of the device may also occur which may contribute to higher morbidity, mortality, and cost.

In November 2002, the FDA expanded the use of the HeartMate device to be implanted permanently in certain terminally ill patients; those who have a severe end-stage CHF, are ineligible for heart transplant, and have a body surface area >1.5 sq. m. It required that the manufacturer (Thoratec) conduct a post-approval study to assess the device's long-term safety and effectiveness for permanent use.

Percutaneous Left Ventricular Assist Device (PLVAD)

Cardiogenic shock is a state of inadequate tissue perfusion due to cardiac dysfunction. It occurs in a variety of settings such as myocardial infarction, post-cardiotomy shock, decompensated chronic heart failure, acute valve failure, and myocarditis. Despite the major advances in the treatment and aggressive perfusion strategies, cardiogenic shock is still associated with high in-hospital mortality rates that range from 40% to 80% depending on the clinical circumstances. The Intra-Aortic Balloon Pump (IABP) is the left ventricular mechanical assistance © 2007 Kaiser Foundation Health Plan of Washington. All Rights Reserved.

device most commonly used to stabilize patients in cardiogenic shock. It decreases afterload, increases coronary perfusion, and improves cardiac output. However, IABP pump delivers an output of only 0.5 L/min, lacks active cardiac support, does not decrease infarct size, or improve clinical outcomes of patients with acute ST-segment elevation myocardial infarction. New technologies such as percutaneous left ventricular assist devices (LVADs) have been developed to provide more effective hemodynamic short-term support for the failing heart. The three main indications for percutaneous LVAD support include: 1. Reversible left ventricular failure to provide temporary circulatory support until recovery or revascularization, 2. Large ischemic area at risk to provide temporary circulatory support during high-risk percutaneous or surgical revascularization, and 3. Bridging therapy to provide temporary circulatory support as a bridge to a permanent surgical assist device or heart transplantation (Burkoff 2006, Windecker 2007, Seyfarth 2008, Cheng 2009).

Currently two percutaneous LVADs are available for clinical use: The TandemHeart and the Impella Recover system. The TandemHeart utilizes a drainage cannula placed via transseptal puncture into the left atrium to aspirate oxygenated blood, which is then injected through a transfugal pump into the femoral artery, establishing a left-atrial-to-femoral arterial bypass. The Impella Recover is based on a miniaturized impeller (microaxial pump) that can be advanced into the left ventricle through an arterial vascular system. It has a caged blood flow inlet that is placed retrograde into the left ventricle to aspirate oxygenated blood, which is then injected by means of a microaxial pump into the ascending aorta establishing a left ventricular to aortic by-pass. The TandemHeart requires both venous and arterial femoral access whereas the Impella Recover system requires only femoral arterial access. Currently two Impella Recover systems are available: The Impella Recover LP 2.5 and the Impella Recover LP 5.0 models. The Impella LP 2.5 (Abiomed Europe GnbH, Aachen, Germany) is a catheter suitable for percutaneous implantation, while the Impella Recover LP 5.0 catheter requires surgical cut of the femoral artery for device insertion (Windecker 2007).

The Impella Recover LP 2.5 is a catheter-based, impeller-driven, axial -flow pump. It has a diameter of 6.4 mm at the body of the pump and 7.3 mm diameter at the level of the outflow opening. A small electric motor is built into the device, and a thin 2.8 mm cable leading to the device contains the electrical power supply, which is connected to an external control unit as well as a purge line connected to a purge perfuser. Through this perfuser, heparin (in a glucose solution) is flushed continuously in the motor housing and throughout the pump, and the patient does not need systemic anticoagulation. A pressure sensor within the device continuously monitors pressure differences between inflow and outflow. The pump is inserted percutaneously in the catheterization laboratory via a standard guidewire through the femoral artery into the left ventricle. The circulatory support provided by the device can be adjusted at nine different levels of speed. At its maximal rotation speed of 50,000 rpm, the pump can deliver an output of up to 2.5 liters of blood per minute from the left ventricle into the ascending aorta. This actively unloads the ventricle, increases the cardiac output, and increases both coronary and end-organ perfusion. The Impella pumps are indicated for temporary use (up to 6 hours) however, it has been reported that the device can be safely left in place to support hemodynamics for up to 5 days. (Seyfarth 2008, Vecchio 2008, Cheng 2009, Wiktor 2010).

Impella Recover 2.5 and 5.0 devices (ABIOMED Inc) have both received FDA clearance for circulatory support for periods up to 6 hours. The current review focuses on the use of the Impella Recover 2.5.

Medical Technology Assessment Committee (MTAC)

LVAD in the treatment of End Stage Heart Failure

08/13/2003: MTAC REVIEW

Evidence Conclusion: The REMATCH trial reviewed was conducted among a highly selected group of patients with end stage heart failure, and contraindication for heart transplantation. The trial compared the patients who received the LVAD to those who were treated medically. The methodology of the trial was generally valid; however, it was not blinded. Blinding in such a trial is not possible, and non-blinding may be a source of observation bias. The authors tried to partly overcome this limitation by using independent blinded observers to measure the outcome events. In this trial survival was higher among patients receiving LVAD vs. those in the optimum medical management group. The difference between the two groups was statistically significant, at one year (NNT=4), but not at 2 years. The two years survival among patients receiving the LVAD was only 22%, and according to the survival graph, the 26 months survival was 8%. The LVAD was associated with serious adverse events. Sepsis and device failure were responsible for the majority of deaths in the LVAD group (41.5%, and 17.1% respectively), and left ventricular dysfunction was the cause of death in 92% of the cases in the medical treatment group. The authors concluded that the quality of life was better among LVAD recipients, however the analysis of QoL was only performed among survivors who were able to complete the questionnaires (35% in the LVAD group, and 18% in the medical treatment group). In conclusion the REMATCH

trial provides some evidence that LVAD may improve survival, however for a short duration, and not without serious adverse events, among a selected group of patients with and end stage heart failure, and who are not candidates for heart transplantation. It does not provide evidence that LVAD may be used as an alternative to transplantation, in patients eligible for a heart transplant.

<u>Articles</u>: The search yielded 32 articles many of which were reviews, opinion pieces, or dealt with the technical aspects of the procedure. One randomized controlled trial, 5 case series and several case reports were identified. The RCT was selected for critical appraisal. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med 2001; 345:1435-43. See Evidence Table.

The use of LVAD in the treatment of End Stage Heart Failure does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

02/14/2011: MTAC REVIEW

Percutaneous Cardiac Support Systems

Evidence Conclusion: The literature search revealed only one small randomized controlled trial that evaluated the safety and efficacy of the Impella Recover LP 2.5 for the treatment of cardiogenic shock caused by myocardial infarction. The trial compared the Impella device with the IABP, the most commonly used device to treat cardiogenic shock. However, the study was too small, blinding and randomization method were not discussed, and it was only powered to detect the difference between the two devices in hemodynamic improvements. It was not powered to evaluate impact on clinical outcomes. The results of the RCT (Evidence table 1) show that the Impella LP 2.5 resulted in better hemodynamic improvement compared to the IABP. However, this was not translated to an improvement in the 30-day survival of the patients in cardiogenic shock after an acute myocardial infarction.

Patients treated with the Impella device tended to have more device-related bleeding, and more limb ischemia.

Articles: The literature search identified one small randomized controlled trial that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock, a meta-analysis of RCTs comparing percutaneous LVAD to IABP for the treatment of cardiogenic shock, and three other case series evaluating the feasibility and safety of the device. The meta-analysis (Cheng 2009) pooled the results of three trials; two evaluated the TandemHeart, and the third evaluated the Impella Recover 2.5 device. The RCT that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock was selected for critical appraisal. Seyfarth M, Sibbing D, Bauer I, A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol 2008; 52:1584-1588. See Evidence Table.

The use of percutaneous cardiac support systems in the treatment of End Stage Heart Failure does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Applicable Codes

Artificial Hearts - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

above are men		
CPT®	Description	
Codes		
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy	
33928	Removal and replacement of total replacement heart system (artificial heart)	
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List	
	separately in addition to code for primary procedure)	

Ventricular Assistive Devices - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®	Description
Codes	
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or

	each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
04/07/2020	07/07/2020 MPC, 07/06/2021 MPC, 07/05/2022 MPC, 07/011/2023 MPC	11/13/2023

Revision History	Description
	Added the LCA A52967
03/12/2020 (VAD)	Added statement for medical director to consult with cardiology re Impella (PLVAD) as needed
04/07/2020	MPC approved to adopt KP National coverage policy. Combined Artificial Heart and Ventricular
	Assistive Devices criteria. Removed deleted codes 0051T, 0052T and 0053T.
07/07/2020	Added CPT codes 33981, 33982 and 33983
07/06/2021	Coding update, added new CPT code 33995
11/13/2023	Updated Medicare coverage article link A52967 which was retired 11/1/2023

MDCRPC Medical Director Clinical Review and Policy Committee MPC Medical Policy Committee

^{**}To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.