Medical Coverage Policy

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Ventricular Assist Devices (VADs), Percutaneous Cardiac Support Systems and Total Artificial Heart

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Related Coverage Resources

External Counterpulsation
Heart, Lung, and Heart-Lung Transplantation

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Overview

This Coverage Policy addresses mechanical circulatory assist devices which include ventricular assist devices (VADs), percutaneous ventricular assist devices (pVADs), permanently implantable aortic counterpulsation VADs and total artificial heart (TAH).

Coverage Policy

Implantable Ventricular Assist Devices (VADs)

A U.S. Food and Drug Administration (FDA)-approved/cleared VAD* is considered medically necessary when ANY of the following criteria is met:

- Individual in acute cardiogenic shock when recovery is expected
- Individual unable to be weaned from cardiopulmonary bypass following cardiac surgery when recovery is expected
- Individual in whom heart transplantation is anticipated and who is otherwise not expected to survive until transplantation
- Individual not expected to be considered a candidate 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 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
- use as a right ventricular assist device (RVAD) for temporary circulatory support 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 thirty days for an individual in cardiogenic shock due to acute right ventricular failure
  - individual is willing and able to be treated with heparin or an appropriate alternative anticoagulation
- use for up to six hours to provide hemodynamic stabilization in an individual in need of cardiopulmonary support

*See Appendix for a list of FDA approved/cleared devices.

Pediatric Implantable Ventricular Assist Devices (VADs)

A U.S. Food and Drug Administration (FDA)-approved Pediatric VAD* is considered medically necessary in a child who is a candidate for cardiac transplantation, when EITHER of the following criteria is met:

- HeartAssist® – 5 Pediatric VAD
  - age 5–16
  - body surface area (BSA) ≥ 0.7 m^2 and < 1.5 m^2
  - in NYHA Class IV end-stage (i.e., left ventriculasur) heart failure refractory to medical therapy
  - 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
- EXCOR® Pediatric Ventricular Assist Device
  - severe isolated left ventricular or biventricular dysfunction
  - requires circulatory support

A VAD in an individual with ANY of the following contraindications to permanent (implantable) placement is considered not medically necessary (this list may not be all-inclusive):

- persistent, recurrent or unsuccessfully-treated major or systemic infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of device placement
- lack of sufficient care-giver support

*See Appendix for a list of FDA approved/cleared devices.

Percutaneous Ventricular Assist Devices (VADs)

A U.S. Food and Drug Administration (FDA)-approved/cleared percutaneous VAD* is considered medically necessary when ANY of the following criteria is met:

- Individual in acute cardiogenic shock
- During high-risk percutaneous coronary interventions (PCI) for **EITHER** of the following:
  - PCI on an unprotected left main or last patent coronary vessel with left ventricular ejection fraction (LVEF) ≤ 35%.
  - PCI for three-vessel disease with LVEF ≤ 30%.
- Up to 14 days in a child or adult with a BSA ≥ 1.5m^2 for the treatment of acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery

A percutaneous ventricular assist device used for any other indication—including off-label use as a long-term alternative to implantable VADs—is considered not medically necessary.

*See Appendix for a list of FDA approved/cleared devices.

Implantable Aortic Counterpulsation Ventricular Assist Devices (VADs)

A permanently implantable aortic counterpulsation VAD for any indication is considered experimental, investigational or unproven.

Total Artificial Heart

The SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) is considered medically necessary in an individual who is transplant-eligible and at risk of imminent death from biventricular failure.

The SynCardia Freedom® Driver System is considered medically necessary in an individual who is clinically stable and discharge is planned following medically necessary implantation of the SynCardia temporary Total Artificial Heart.

The SynCardia temporary Total Artificial Heart or SynCardia Freedom Driver System is considered not medically necessary for any other indication.

See Appendix A for a list of FDA approved/cleared devices.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Implantable Ventricular Assist Devices (VADs)

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

CPT®* Codes	Description
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

Percutaneous Ventricular Assist Devices (VADs)

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

CPT®* Codes	Description
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion

Implantable Aortic Counterpulsation Ventricular Assist Devices (VADs)

Considered Experimental/Investigational/Unproven when used to report a permanent implantable aortic counterpulsation ventricular assist device:

CPT®* Codes	Description
33999	Unlisted procedure, cardiac surgery

Total Artificial Heart

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

CPT®* Codes	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33999†	Unlisted procedure, cardiac surgery

†**Note: Considered Medically Necessary when used to report revision or replacement of components only of a replacement heart system (artificial heart) and when criteria in the applicable policy statements listed above are met.**

HCPCS Codes	Description
L8698††	Miscellaneous component, supply or accessory for use with total artificial heart system

††**Note: Considered Medically Necessary when used to report a component, supply, or accessory for use with a total artificial heart system and when criteria in the applicable policy statements listed above are met.**

Considered Medically Necessary when used to report the SynCardia Freedom® Driver System:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.**

General Background

Ventricular Assist Devices:

Ventricular assist devices (VADs) are mechanical pumps, also known as mechanical circulatory support (MCS) devices, that help a weak heart move blood through the body by pulling blood from the left ventricle and sending it into the aorta, taking over much of the heart's work. They are used in a variety of conditions including postcardiotomy shock, acute myocarditis, and end-stage heart failure when medical therapy isn't effective and can serve as temporary support until recovery is achieved or heart transplant, or as a long-term therapy when transplant isn't possible. VADs may be extracorporeal, paracorporeal, implantable with percutaneous power support, or fully implantable and can provide left (LVAD), right (RVAD), or biventricular (BiVAD) support.

VADs provide stronger, longer-lasting support than intra-aortic balloon pumps (IABP), which offer only modest afterload reduction, or extracorporeal membrane oxygenation (ECMO), which also supports the lungs by way of an oxygenator but is intended for short-term use. Because VADs require complex management, initial care takes place in specialized centers and intensive care units. Once stable, many patients transition to outpatient follow-up with portable drivers and regular check-ups (Dumitru, 2025; Selzman, 2024).

Terms such as *bridge-to-transplant*, *destination therapy*, and *bridge-to-decision* are commonly used in clinical literature. However, they are intentionally omitted from the coverage policy statements due to the lack of universally accepted definitions, which may lead to inconsistent interpretation.

Implantable Ventricular Assist Devices:

Implantable ventricular assist devices (VADs) are surgically implanted mechanical pumps designed to support patients with advanced heart failure by assisting the left ventricle in pumping blood to the rest of the body. These devices, such as the HeartMate 3 and HeartWare systems, are typically placed via median sternotomy with the inflow cannula positioned at the apex of the left ventricle and the outflow graft connected to the ascending aorta. Implantable VADs are intended for long-term use, either as a bridge to transplant, destination therapy, or bridge to recovery. They differ significantly from percutaneous VADs, which are inserted via catheter-based techniques (e.g., through the femoral artery) and are used for short-term hemodynamic support in acute settings. Additionally, implantable VADs are distinct from total artificial hearts (TAHs), which replace both ventricles entirely and are used in cases of biventricular failure. Unlike TAHs, VADs assist rather than replace native cardiac function, and unlike percutaneous devices, they are designed for chronic support and require surgical implantation (Selzman, 2024).

Contraindications to Implantable VADs
The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support (MCS) address the issue of patient selection for permanent pump implantation. Candidate selection is one of the most important determinants of successful operative and long-term outcomes for patients receiving implantable MCS. Several factors must be considered during the patient assessment for an MCS device beyond the presence of advanced heart failure. Comorbidities, surgical risk, expectation of benefit, psychological and social support, and the type of device must also be determined prior to implant. Many patients also require a period of aggressive pre-operative medical therapy to optimize their condition prior to MCS (Feldman, et al.,

2013). Absolute contraindications to receiving a permanent implantable VAD include irreversible hepatic, renal, or neurological disease, medical nonadherence, and severe psychosocial limitations. Relative contraindications include: age >80 years for destination therapy, obesity or malnutrition, musculoskeletal disease that impairs rehabilitation, active systemic infection or prolonged intubation, untreated malignancy, severe peripheral vascular disease, active substance abuse, unmanaged psychiatric disorder, and lack of social support (Cook, et al., 2017).

U.S. Food and Drug Administration (FDA)
Implantable ventricular assist devices (VADs) currently approved or cleared by the FDA are regulated as Class III medical devices, which are subject to the highest level of regulatory control due to their life-supporting and life-sustaining functions. These devices are typically approved through one of three regulatory pathways: Premarket Approval (PMA) for devices requiring rigorous scientific evidence of safety and effectiveness, Humanitarian Device Exemption (HDE) for devices intended to treat or diagnose conditions affecting fewer than 8,000 individuals annually in the U.S., and Premarket Notification [510(k)] for devices shown to be substantially equivalent to legally marketed devices. Implantable VADs are classified under the FDA product code OKR and designated as ventricular bypass (assist) devices. Common attributes across all implantable VADs include their role in providing mechanical circulatory support for patients with advanced heart failure, their use in both adult and pediatric populations, and their design for long-term or bridge-to-transplant therapy. Their primary function is to support or replace the pumping function of the heart, either unilaterally or bilaterally, depending on the clinical indication (FDA, 2025a; FDA, 2025b; FDA 2025c).

See Appendix for a list of FDA approved/cleared devices.

Literature Review
Multiple studies, including randomized controlled trials, prospective cohort studies, and retrospective analyses, have evaluated the safety and efficacy of implantable ventricular assist devices (VADs) in patients with advanced or end-stage heart failure. Devices have been studied across a range of clinical scenarios, including use in patients with potentially reversible ventricular dysfunction (such as those experiencing acute myocarditis, acute cardiogenic shock, or those unable to be weaned from cardiopulmonary bypass following cardiac surgery), in individuals awaiting heart transplantation, and in patients with advanced heart failure who are not transplant candidates and are unlikely to recover cardiac function. Sample sizes ranged from small cohorts (n=24) to large multicenter trials (n=466), with follow-up durations extending from 30 days to two years. Across studies, VADs demonstrated high survival rates at 30 days, six months, and one year, with some reporting up to 81% survival at one year. Adverse events such as bleeding, stroke, infection, and device malfunction were noted, though rates varied by device type and patient population. Pediatric data from the Berlin Heart EXCOR study showed a high incidence of neurological events, yet survival outcomes were favorable compared to ECMO. Despite the frequency of complications, authors consistently concluded that VADs offer a life-saving option for patients who would otherwise face poor prognoses. Limitations across studies included small sample sizes, lack of control groups receiving optimal medical therapy alone, and variability in patient selection criteria. Nonetheless, the collective evidence supports the efficacy of VADs when criteria are met, given their ability to improve survival and quality of life in patients with otherwise refractory heart failure. Randomized controlled trials (RCTs) in this area are rare, primarily due to ethical concerns associated with withholding a potentially life-saving intervention from critically ill patients (Khoufi, 2025; Rohde, et al., 2023; Mehra, et al., 2018; Krabatsch, et al., 2017; Mehra, et al., 2017; Ozturk, et al., 2017; Rogers, et al., 2017; Uriel, et al., 2017; Thomas, et al., 2011; Jordan, et al., 2015; Fraser, et al., 2012; John, et al., 2011).

Percutaneous Ventricular Assist Devices:

Percutaneous ventricular assist devices (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, percutaneous VADs are minimally invasive and do not require surgical implantation, and unlike IABP, percutaneous VADs provide hemodynamic support independent of left ventricular function. 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 as an alternative to IABP for use in high-risk percutaneous coronary intervention (PCI) procedures.

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)
Percutaneous VADs are considered Class II or Class III medical devices and are regulated by the FDA under either the 510(k) pathway, Premarket Approval (PMA), or Humanitarian Device Exemption (HDE). These devices are intended to provide temporary circulatory support during high-risk PCI or ongoing cardiogenic shock as defined by their FDA indication. Percutaneous VADs are classified under the FDA product codes KFM, OZD, PYX, DWA (FDA, 2025a; FDA, 2025b; FDA 2025c).

See Appendix for a list of FDA approved/cleared devices.

Literature Review

High-Risk Percutaneous Intervention: Multiple studies, including randomized controlled trials (RCTs), observational registries, case series, and meta-analyses, encompassing over 3,000 individuals, have evaluated the safety and efficacy of percutaneous ventricular assist devices (pVADs), primarily the Impella 2.5, in high-risk PCI populations. Follow-up durations ranged from 30 days to 42 months. Patients were typically older, had low left ventricular ejection fractions (LVEF ≤ 35%), and presented with complex coronary artery disease, including multivessel and left main involvement. In the PROTECT II RCT, Impella showed a trend toward reduced major adverse events (MAE) at 90 days compared to intra-aortic balloon pump (IABP), though 30-day differences were not statistically significant. Registry data and case series demonstrated high procedural success rates (up to 99%), low short-term mortality (3.7%–10%), and improvements in hemodynamic and functional parameters. A meta-analysis found no significant difference in

mortality between pVADs and IABP but noted reduced repeat revascularization and increased bleeding risk with pVADs. Limitations across studies include small sample sizes, observational designs, lack of standardized criteria for device use, and heterogeneity in patient populations and procedural protocols. Despite these limitations, the collective evidence supports the safety and procedural efficacy of pVADs in high-risk PCI (Shi, et al., 2019; Ait Ichou, et al., 2018; Rios, et al., 2018; Ouweneel, et al., 2017; Cohen, et al., 2015; Maini, et al., 2012; O'Neil, et al., 2012; O'Neill, et al., 2012; Shah, et al., 2012; Alasnag, et al., 2011; Dixon, et al., 2009; Sjauw, et al., 2009; Seyfarth, et al., 2008).

Cardiogenic Shock: Multiple randomized controlled trials (RCTs), meta-analyses, and registry studies have evaluated the safety and efficacy of percutaneous ventricular assist devices (pVADs), including Impella and TandemHeart, in patients with cardiogenic shock. These studies generally demonstrate that pVADs provide superior hemodynamic support compared to intra-aortic balloon pump (IABP), with improvements in cardiac index, mean arterial pressure, and reductions in pulmonary capillary wedge pressure and arterial lactate. Sample sizes ranged from small RCTs (n=26–48) to larger meta-analyses and registries (up to n=442), with follow-up durations from 30 days to 6 months and beyond. Despite improved hemodynamics, most studies did not show a statistically significant reduction in short-term mortality compared to IABP, although one meta-analysis (Tariq et al., 2024) reported reduced 6-month mortality with Impella. Device-related complications were consistently higher with pVADs, including major bleeding, limb ischemia, hemolysis, and sepsis. Limitations across studies included small sample sizes, heterogeneous patient populations, retrospective designs, lack of standardized control treatments, and potential publication bias. Overall, the evidence supports the use of pVADs as medically necessary in select high-risk patients undergoing PCI when criteria are met, particularly for short-term circulatory support in cardiogenic shock, while acknowledging the need for careful patient selection due to elevated complication risks (Tariq, et al., 2024; Batsides, et al., 2018; Rios, et al., 2018; Thiele, et al., 2017; Ouweneel, et al., 2017; Lauten, et al., 2013; Shah, et al., 2012; Kar, et al., 2011; Cheng, et al., 2009; Seyfarth, et al., 2008; Burkhoff, et al., 2006; Thiele, et al., 2005).

Tariq et al. (2024) conducted a meta-analysis of four randomized controlled trials (RCTs) involving 442 patients to evaluate the efficacy and safety of Impella compared to standard of care (SOC) in patients with cardiogenic shock (CS) following acute myocardial infarction (AMI). The intervention group received Impella, while the control group received SOC. SOC was not well defined, but was implied to be inotropic support and/or intra-aortic balloon pump. Inclusion criteria required patients to have CS as a complication of AMI, and studies were excluded if they did not report the preferred outcomes or included subjects without CS. The primary outcome was 6-month all-cause mortality, with secondary outcomes including 30-day mortality, major bleeding, limb ischemia, sepsis, and left ventricular ejection fraction (LVEF). Follow-up durations included 30 days and 6 months. The study did not report on subjects lost to follow-up. Impella significantly reduced 6-month all-cause mortality (P = .03), but showed no significant difference in 30-day mortality (P = .95). Use of Impella was associated with increased odds of major bleeding (P = .03), limb ischemia (P = .01), and sepsis (P = .01). No significant difference was found in LVEF (P = .11). Limitations included a small number of RCTs, lack of subgroup analyses, and potential publication bias. The authors concluded that "Although the use of Impella has been associated with an increase in complications such as major bleeding, sepsis, and limb ischemia, these complications do not translate into increased mortality."

Acute Right Heart Failure: Marta et al. (2024) conducted a single-center retrospective observational study to evaluate the clinical outcomes of 18 adult patients who developed right ventricular failure (RVF) following cardiac surgery with cardiopulmonary bypass and were treated with the Impella-RP microaxial pump. Women made up 17% of the study population. The intervention involved Impella-RP support, with no control or comparator group. Inclusion criteria required elevated lactate (>8 mmol/L), vasoconstrictor use (>0.1 γ), at least one inotropic drug,

and CVP >15 mmHg. The primary outcome was 30-day survival, with secondary outcomes including hemodynamic effects, reduced inotrope use, and device complications. The study reported a 30-day survival rate of 61.1% and an overall mortality rate of 38.9%. The study found significant improvement in cardiac index ($p = 0.032$) and noted that patients undergoing isolated coronary artery bypass grafting had significantly better survival ($p = 0.036$). Adverse events such as bleeding and acquired von Willebrand syndrome were not significantly associated with mortality. Limitations included the small sample size, single-center design, and lack of baseline data on several clinical parameters. The authors concluded that Impella-RP is a safe and effective treatment for select patients with RVF, though survival is influenced by multiple factors.

The RECOVER RIGHT pivotal study, a prospective, multi-center, non-randomized study, was the basis for the FDA HDE approval of the Impella RP System. The primary objective for the study was to assess safety and effectiveness of the use of the Impella RP device in patients (n=30) with right ventricular failure (RVF) refractory to medical treatment who require hemodynamic support. Inclusion criteria were patients who have developed signs of RVF either within 48 hours post-implantation of an FDA approved implantable surgical LVAD (Cohort A) or subsequent to post-cardiotomy cardiogenic shock within 48 hours post-surgery or post myocardial infarction (Cohort B). Eighteen subjects (60%) were enrolled in Cohort A and 12 subjects (40%) were enrolled in Cohort B. The primary endpoint of survival at 30 days or discharge post device removal (whichever is longer), or to induction of anesthesia for the next longer-term therapy was achieved in 73% of the study population, with 83% in cohort A and 58% in cohort B. The secondary safety endpoint was determined by the rates of the following adverse events at 30 days or discharge (whichever is longer), or at induction of anesthesia for a longer term therapy, including heart transplant or implant of a surgical RVAD (as a bridge-to-recovery or bridge-to-transplant): death (any cause of death and cardiac death); major bleeding; hemolysis; pulmonary embolism; tricuspid/pulmonary valve dysfunction (defined as tricuspid/pulmonic valve injury resulting in increased valve regurgitation versus baseline). The summary overall conclusions state that the RECOVER RIGHT was the first study of a percutaneous RVAD in patients with RVF refractory to medical treatment who had very limited therapeutic options. In the studied patient population, the use of the Impella RP device provided adequate circulatory support to reverse shock and to restore normal hemodynamic parameters and achieved an overall survival rate of 73% at 30 days or discharge (whichever is longer) or to a long-term therapy. The Impella RP device had a reasonable overall safety profile, with reliable percutaneous insertion and a low incidence of bleeding and vascular complications (Anderson, et al., 2015).

Percutaneous Ventricular Assist Device for Any Other Indication: While percutaneous ventricular assist devices (pVADs) have demonstrated utility in specific clinical scenarios such as high-risk percutaneous coronary intervention (PCI), cardiogenic shock, and right heart failure, there is a lack of regulatory approval and supporting peer-reviewed literature for other indications. Therefore, use of pVADs for any other indication is considered not medically necessary.

Percutaneous mechanical circulatory support (MCS) devices, such as Impella, are increasingly being used in clinical practice. While these devices are FDA-approved for short-term support, emerging off-label use for extended durations—particularly as an alternative to durable ventricular assist devices (VADs)—raises ethical concerns that warrant clarification. Specifically, long-term use of Impella may allow patients to qualify for higher heart transplant waitlist statuses (e.g., OPTN Status 2) than they would with a durable VAD (typically Status 4). This practice may inadvertently influence transplant prioritization by maintaining patients in higher urgency categories, despite comparable clinical stability. Such strategic use risks undermining the equity and intent of the organ allocation system, which is designed to prioritize patients based on medical urgency and fairness. To promote transparency and uphold ethical standards, off-label, long-term use of percutaneous MCS devices for the sole purpose of optimizing transplant waitlist status is considered not medically necessary. Coverage decisions will be guided by clinical

evidence, regulatory approvals, and alignment with national transplant policy frameworks, including those established by OPTN (OPTN, 2025; FDA, 2025b; FDA, 2025c).

The Impella 5.5 with SmartAssist system has been proposed for use as a bridge to transplantation in adults with end-stage heart failure. Literature is limited to a single case series reporting on outcomes in four individuals who all underwent successful heart transplantation after 81, 79, 65, and 54 days of Impella support. The study reported that one individual experienced 2 separate episodes of acute left posterior cerebral artery infarct on days 30 and 62 of support. There is insufficient evidence in the peer reviewed published literature to support the safety and efficacy of percutaneous VADs as a bridge to transplantation in adults with end stage heart failure (Zaky, et al., 2023).

Implantable Aortic Counterpulsation Ventricular Assist Devices (VADs)

Permanently implantable aortic counterpulsation ventricular assist devices have been proposed as a bridge to recovery for patients with acute or chronic heart failure. These devices employ a counterpulsation device that is surgically implanted in the aorta, which inflates during diastole to reduce end diastolic ventricular pressure on a long-term basis without re-routing blood flow (Kontogiannis, et al., 2016; Gafoor, et al., 2015). There are scarce data in the published, peer-reviewed scientific literature regarding the safety and effectiveness of implantable aortic counterpulsation VADs in the treatment of heart failure.

U.S. Food and Drug Administration (FDA)
To date, there are no implantable aortic counterpulsation ventricular assist devices that have received FDA approval or clearance (FDA, 2025a; FDA, 2025b; FDA 2025c).

Total Artificial Heart
Heart failure can develop from any condition that overloads, damages, or reduces the efficiency of the heart muscle, impairing the ability of the ventricles to fill with or eject blood. Heart muscle may be damaged by myocardial infarction, coronary artery disease, infection, toxic chemical exposure, or years of untreated hypertension or heart valve abnormality. Treatment of heart failure includes pharmacologic interventions, including diuretics, angiotensin-converting enzyme inhibitors, vasodilators, digitalis, and beta-blockers. Pharmacologic therapy is ineffective in approximately 40% of heart failure patients, however. Heart transplantation is the most effective treatment for advanced heart failure, with most transplant centers achieving one-year survival rates of 85% or greater. Most transplant recipients can expect a ten-year survival of approximately 50%. The demand for donor hearts far exceeds the available supply, however. Cardiac transplant waiting lists have the highest mortality (30%) of any solid organ waiting list.

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. External or implantable ventricular assist devices (VADs) are therefore used for many patients with end-stage heart failure while awaiting transplantation. Timely use of VADs may be successful in preventing further deterioration and reversing metabolic, cellular, and nutritional compromise. The temporary use of these mechanical devices is referred to as "bridging" to transplant. VADs are usually inadequate as a bridge to transplant for patients with severe biventricular disease, and two paracorporeal devices may be needed. VADs may be contraindicated, however, in those with aortic regurgitation, cardiac arrhythmias, left ventricular thrombus, aortic prosthesis, acquired ventricular septal defect, or irreversible biventricular failure. A total artificial heart (TAH) is a mechanical circulatory device that has been used primarily to maintain patients until a suitable donor heart is available for transplantation. A fully implantable heart may also be considered as a permanent cardiac replacement, or "destination therapy", for patients with end-stage heart disease who are not candidates for heart transplantation (Bartoli, 2011; Copeland, et al., 2004b).

U.S. Food and Drug Administration (FDA)
SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ): The SynCardia Temporary Total Artificial Heart (TAH-T) is a Class III medical device approved by the FDA through the Premarket Approval (PMA) pathway (PMA #P030011) on October 15, 2004. It is indicated for use in transplant-eligible patients with end-stage biventricular heart failure who are at imminent risk of death and require circulatory support as a bridge to heart transplantation. The device is intended for in-hospital use as a temporary replacement for both ventricles and heart valves. Contraindications include patients who are not eligible for heart transplantation, those with insufficient anatomical space to accommodate the device (e.g., body surface area < 1.7 m^2 or sternum-to-vertebral body distance < 10 cm), and individuals who cannot be adequately anticoagulated (FDA, 2025b).

The Freedom Driver is a wearable, battery-powered pneumatic driver approved by the FDA as part of a PMA supplement (P030011/S020) for use in clinically stable cardiac transplant candidates who have been implanted with the TAH-T. Once a patient is deemed stable post-implantation, they may transition from the in-hospital Companion 2 Driver to the Freedom Driver and be discharged to wait for a donor heart at home (FDA, 2025b).

See Appendix for a list of FDA approved/cleared devices.

Literature Review
The evidence supporting the use of Total Artificial Hearts (TAHs) in individuals with imminent risk of death from biventricular failure includes multiple retrospective studies, case series, and one multicenter controlled clinical trial. Across these studies, TAHs—primarily the SynCardia temporary TAH—were used in patients with refractory cardiogenic shock or terminal heart failure, often supported by mechanical ventilation or extracorporeal life support. Sample sizes ranged from 13 to 127 patients, with support durations varying widely (mean durations from ~46 to ~101 days). Survival to transplant ranged from 56% to 79%, with post-transplant survival rates at one year typically between 56% and 90%, and up to 76% at ten years in some cohorts. Adverse events included stroke, infection, multi-organ failure, and device-related complications, though no device malfunctions directly led to death. Limitations across studies included retrospective designs, single-center data, evolving patient selection criteria, and changes in immunosuppressive regimens over time. Despite these limitations, the collective evidence demonstrates that TAHs offer a viable and effective treatment option for patients with irreversible biventricular failure, with acceptable safety profiles and encouraging long-term outcomes (David, et al., 2020; Nguyen, et al., 2017; Demondion, et al., 2013; Kirsch, et al., 2013; Copeland, et al., 2012; Roussel, et al., 2009; Drakos, et al., 2006; Copeland, et al., 2004; Leprince, et al., 2003).

Professional Societies/Organizations

American College of Cardiology (ACC): In a 2025 clinical guidance document on the evaluation and management of cardiogenic shock (CS) (Sinha, et al., 2025), the ACC provided the following recommendations for the use of temporary MCS with the disclaimer that RCTs examining tMCS in CS have been focused on STEMI-CS and have been limited by sample size, study design, patient selection, timing, and other key limitations. The writing committee also noted that several proposed therapies that are included in the recommendations have yet to be rigorously studied in well-designed RCTs. No specific grading or level of evidence was provided:

- "Classic" Shock with hypoperfusion ((i.e., lactate ≥2 mmol/L, major renal & hepatic dysfunction) + hypotension (i.e., SBP <90 mmHg OR current treatment consists of 1 drug or device))
    - LV dominant: Consider IABP or Impella CP

    - RV dominant of BiV: Consider Pro-Tek Duo/CentriMag OR Impella RP Flex +/- Impella CP OR Impella 5.5
- "Deteriorating" Shock with hypoperfusion ((i.e., lactate ≥4 mmol/L, worsening renal & hepatic dysfunction) + hypotension (i.e., Escalating pressors OR current treatment consists of 2 drugs or devices))
    - LV dominant: Consider Impella CP OR Impella 5.5 OR VA-ECMO +/- LV vent
    - RV dominant or BiV: Consider VA-ECMO +/- LV vent OR Impella 5.5 +/- ProTek Duo/CentriMag OR Impella RP Flex

International Society for Heart and Lung Transplantation (ISHLT)/Heart Failure Society of America (HFSA): In a 2023 guideline on acute mechanical circulatory support (MCS) (Bernhardt, et al., 2023), the ISHLT/HFSA provided evidence-based recommendations for the use of implantable and percutaneous ventricular assist devices in the management of cardiogenic shock, percutaneous coronary intervention (PCI), and right heart failure. The guideline is based on expert consensus and a review of available literature, acknowledging the limited high-quality randomized trial data. ISHLT/HFSA stated that CS complicating AMI remains the predominant etiology of cardiogenic shock accounting for up to 80% of cases and remains a deadly complication with a mortality rate of 30–50%. For left ventricular support in cardiogenic shock, the guideline recommends devices such as Impella CP, 5.0, and 5.5, which may be selected based on a target cardiac index of >2.2 L/min/m². In the context of PCI, early initiation of Impella prior to revascularization is associated with improved survival and myocardial recovery. For right ventricular failure, Impella RP is recommended, with supporting data from the RECOVER RIGHT study. In cases of biventricular failure, combined support using VA-ECMO, bilateral centrifugal or axial flow pumps is advised. CentriMag is noted for its versatility in providing LVAD, RVAD, or BiVAD support, while TandemHeart offers hemodynamic improvement but presents procedural complexity due to transseptal access.

- "Impella CP, 5, or 5.5 can be considered for adult patients with CS (Class of recommendation II; Level of evidence B).
- Reported complications of Impella placement include vessel perforation, extensive bleeding at insertion site, rapid progression of cardiac failure or acute RV failure. These should be addressed as clinically appropriate (Class of recommendation I; Level of evidence B).
- ProtekDuo or Impella RP can be considered for acute RV failure (Class of recommendation II; Level of evidence B).

Adverse events associated with these devices include bleeding, vascular injury, hemolysis, and increased mortality when used outside of protocol. Limitations of the literature include small sample sizes, nonrandomized designs, and lack of survival benefit despite hemodynamic improvements. The guideline concludes that temporary MCS should be considered for immediate stabilization, bridge to recovery, or bridge to durable therapy. Pre-PCI LV unloading is emphasized as a strategy to reduce infarct size and improve outcomes.

American Heart Association (AHA): While the AHA doesn't provide specific endorsements regarding the use of percutaneous ventricular assist devices, they do provide clinical practice suggestions based on available evidence and expert consensus in their 2022 scientific statement for escalating and de-escalating temporary mechanical circulatory support in cardiogenic shock. They suggest that percutaneous ventricular assist devices may be appropriate for patients with significant cardiogenic shock, particularly when there is evidence of hypoperfusion, elevated lactate, or hemodynamic instability. Impella CP and TandemHeart are identified as viable options for initial left-sided support in AMI-CS and HF-CS, with Impella 5.5 or VA-ECMO recommended for more severe cases. Device selection should be guided by invasive hemodynamic profiling, imaging, and laboratory data, and decisions should be made by an interdisciplinary shock team. These recommendations are based on observational data, expert consensus, and pragmatic

clinical experience, acknowledging the lack of robust randomized controlled trials. Additionally, while the document does not provide a dedicated section on high-risk PCI, it notes that in select patients with AMI at risk for shock, deployment of a pVAD such as Impella before PCI may provide hemodynamic stabilization that facilitates complex coronary revascularization. This strategy is suggested in cases where early support may improve outcomes, although routine use of pVADs in all AMI-CS patients is not supported due to insufficient randomized data. These suggestions are based on registry data and small trials indicating potential survival benefits when Impella is used before or immediately after PCI (Geller, et al., 2022).

American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation: In a guidance document for mechanical circulatory support (MCS), the American Association for Thoracic Surgery/International Society for Heart and Lung Transplantation (Kirklin, et al., 2020) gave the following recommendations for MCS techniques in cardiogenic shock:

- "IABP support is recommended for cardiogenic shock complicating acute myocardial infarction, but additional mechanical support may be needed if prompt hemodynamic improvement is not forthcoming.
- Percutaneous LV to aorta pumps of appropriate size should be considered for cardiogenic shock from primary LV failure.
- Percutaneous right ventricular assist device support should be considered for cardiogenic shock from primary right ventricular failure."

The guidance document also gave the following recommendations for the use of biventricular support:

- "The possibility of biventricular support should be included in the surgical plan if biventricular failure is documented with CI<2.0 L/min/m2, right atrial pressure>17 mm Hg, and CVP/PCWP ratio>0.63.
- Patients who undergo placement of temporary MCS (percutaneous VAD or ECMO) should have right ventricle function evaluated at regular intervals; if it remains poor and patient is a transplant candidate, consideration for biventricular support or TAH is advisable.
- Patients who received an LVAD as bridge to transplant and remain with poorly controlled right ventricular failure (with or without a temporary right VAD) should be considered for longer-term biventricular support or TAH before end-organ dysfunction ensues."

The Society for Cardiovascular Angiography and Interventions (SCAI), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS), American Heart Association (AHA), and American College of Cardiology (ACC): The Society for Cardiovascular Angiography and Interventions (SCAI), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS), American Heart Association (AHA), and American College of Cardiology (ACC) "2015 Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care" states that the availability of percutaneous mechanical circulatory support (MCS) has broadened therapeutic options for patients that require hemodynamic support. A variety of devices are now available, each with specific technical and clinical nuances. Definitive clinical evidence is in many cases either unavailable or controversial.

The following consensus-based summary statements are based upon the anticipated hemodynamic effects and risks, clinical outcomes data as well as knowledge gap:

- "Percutaneous MCS provides superior hemodynamic support compared to pharmacologic therapy. This is particularly apparent for the Impella and Tandem-Heart devices. These devices should remain available clinically and be appropriately reimbursed.
- Patients in cardiogenic shock represent an extremely high risk group in whom mortality has remained high despite revascularization and pharmacologic therapies. Early placement of an appropriate MCS may be considered in those who fail to stabilize or show signs of improvement quickly after initial interventions.
- MCS may be considered for patients undergoing high-risk PCI, such as those requiring multi-vessel, left main, or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased ejection fraction or elevated cardiac filling pressures.
- In the setting of profound cardiogenic shock, IABP is less likely to provide benefit than continuous flow pumps including the Impella CP and TandemHeart. ECMO may also provide benefit, particularly for patients with impaired respiratory gas exchange.
- Patients with acute decompensated heart failure may benefit from early use of percutaneous MCS when they continue to deteriorate despite initial interventions. MCS may be considered if patients are candidates for surgically implanted VADs or if rapid recovery is expected (e.g., fulminant myocarditis or stress-induced cardiomyopathy).
- When oxygenation remains impaired, adding an oxygenator to a TandemHeart circuit or use of ECMO should be considered based upon local availability.
- There are insufficient data to support or refute the notion that routine use of MCSs as an adjunct to primary revascularization in the setting of large acute myocardial infarction is useful in reducing reperfusion injury or infarct size. Exploratory studies are underway.
- MCSs may be used for failure to wean off cardiopulmonary bypass, considered as an adjunct to high-risk electrophysiologic procedures when prolonged hypotension is anticipated, or rarely, for valvular interventions.
- Severe biventricular failure may require use of both right- and left-sided percutaneous MCS or venoarterial ECMO. Certain patients may respond to LVAD implantation with inotropes and/or pulmonary vasodilators to support the right heart. MCS may also be considered for isolated acute RVF complicated by cardiogenic shock.
- Registries and randomized controlled trials comparing different strategies in different clinical scenarios are critically needed (Rihal, et al., 2015)."

The American Heart Association, American College of Cardiology, and Heart Failure Society of America: The American Heart Association, American College of Cardiology, and Heart Failure Society of America 2022 clinical practice guideline for the management of heart failure states that mechanical circulatory support (MCS) is an option for patients with advanced heart failure with reduced ejection fraction (HFrEF) to prolong life and improve functional capacity. The guideline includes the following recommendations for the use of MCS:

- "In select patients with advanced HFrEF with NYHA class IV symptoms who are deemed to be dependent on continuous intravenous inotropes or temporary MCS, durable LVAD implantation is effective to improve functional status, quality of life, and survival. (Class 1 (strong) recommendation; Level A (high) quality of evidence)
- In select patients with advanced HFrEF who have NYHA class IV symptoms despite guideline-directed medical therapy (GDMT), durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality (Class 2a (moderate) recommendation; Level B-R (moderate) quality of evidence)."
- "In patients with advanced HFrEF and hemodynamic compromise and shock, temporary MCS, including percutaneous and extracorporeal ventricular assist devices, are reasonable as a "bridge to recovery" or "bridge to decision (Class 2a (moderate) recommendation; Level B-NR (moderate) quality of evidence) (Heidenreich, et al., 2022)."

The Heart Failure Society of America (HFSA): The Heart Failure Society of America (HFSA) published the following recommendation in the 2010 Comprehensive Heart Failure Practice Guideline:

- "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.
- Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center (Lindenfeld, et al., 2010)."

The American College of Cardiology Foundation/American Heart Association (ACCF/AHA): The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) "2013 Guidelines for the Management of ST-Elevation Myocardial Infarction" (O'Gara et al., 2013) include the following recommendations relevant to mechanical support in treatment of cardiogenic shock:

- "Alternative left ventricular (LV) assist devices for circulatory support may be considered in patients with refractory cardiogenic shock."

American Heart Association: In a statement on the use of mechanical circulatory support, the American Heart Association indicated that some patients are too profoundly ill with multisystem organ failure to benefit from the best MCS and aggressive inotropic therapy and that complex decisions about candidacy for transplantation or MCS are best made by an experienced multidisciplinary team. While it may become appropriate for smaller programs to implant elective destination therapy MCS in highly selected patients, more acutely ill patients should be referred to quaternary care hospitals that are accustomed to the management of such patients.

The statement makes reference to MCS that may be used as a first step when rapid support is necessary in patients with cardiogenic shock who are at too high a risk for implantation of a durable (i.e., long-term) device, or as an alternative if recovery is possible. In the latter scenario, a bridge with a nondurable (i.e., temporary) MCS device provides stabilization and permits clarification and potential reversal of other medical issues thet may interfere with a satisfactory outcome after transplantation or long-term device placement. The following are included in a list of nondurable MCS devices that may be used as a bridge to recovery and for temporary support until more definitive therapies can be used in patients in whom myocardial recovery does not occur: intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO), BVS 5000, AB5000, Thoratec pVAD, CentriMag, TandemHeart, and Impella. The statement also suggests that nondurable MCS may be used to determine neurological recovery or to stabilize potentially reversible comorbidities in patients with cardiogenic shock and potential candidates for transplantation.

The scientific statement includes the following recommendations:

- "MCS for bridge to transplant (BTT) indication should be considered for transplant-eligible patients with end-stage heart failure (HF) who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation.
- Implantation of MCS in patients before the development of advanced HF (i.e., hyponatremia, hypotension, renal dysfunction, and recurrent hospitalizations) is associated with better outcomes. Therefore, early referral of advanced HF patients is reasonable.
- MCS with a durable, implantable device for permanent therapy or destination therapy (DT) is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and

the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation.
- Elective rather than urgent implantation of destination therapy (DT) can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies.
- Urgent nondurable MCS is reasonable in hemodynamically compromised HF patients with end organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile.
- Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS.
- Long-term MCS is not recommended in patients with advanced kidney disease in whom renal function is unlikely to recover despite improved hemodynamics and who are therefore at high risk for progression to renal replacement therapy. Long-term MCS as a bridge to heart–kidney transplantation might be considered on the basis of availability of outpatient hemodialysis (Peura, et al., 2012)."

The American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Intervention (ACCF/AHA/SCAI): The American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Intervention (ACCF/AHA/SCAI) "Guideline for Percutaneous Coronary Intervention" (Levine et al., 2011) includes the following recommendation:

- "Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients."

High risk patients may include those undergoing unprotected left main or last-remaining-conduit PCI, those with severely depressed ejection fraction patients undergoing PCI of a vessel supplying a large territory, and/or those with cardiogenic shock. The guideline summarizes the limited evidence available on the use of percutaneous VADs, and states that patient risk, hemodynamic support, ease of application/removal, and operator and laboratory expertise are all factors involved in consideration of use of these devices. With devices that require large cannula insertion, the risk of vascular injury and related complications are important considerations regarding necessity and choice of device.

The following recommendation is given regarding cardiogenic shock:

- "A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy."

The guideline addresses procedural considerations for PCI in patients with cardiogenic shock, including pharmacological therapies, endotracheal intubation and mechanical ventilation with positive end-expiratory pressure for patients with respiratory failure, placement of a temporary pacemaker for patients with bradycardia or high-degree atrioventricular heart block, and use of a pulmonary artery catheter to provide information to dose and titrate inotropes and pressures. The authors also state, "Further hemodynamic support is available with IABP counterpulsation or percutaneous LV assist devices, although no data support a reduction in mortality rates."

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

According to a scientific statement from the American Heart Association on social determinants of health (SDOH) in the care of patients with heart failure (HF), there are an estimated 550,000 new cases of HF diagnosed each year accounting for more than 1.9 hospitalizations and $31 billion annually nationwide. The statement identifies several downstream SDOH compounding the complexity of HF management including: socioeconomic position; access to care; environment; race, ethnicity, sex, age, and sexual minorities; social support; and health literacy. The authors found that compared to whites, Blacks have an increased prevalence of HF and disproportionately poor outcomes. This disparity was found to be attributed to, in part, a higher prevalence of risk factors such as uncontrolled hypertension, endothelial dysfunction, and deleterious genetic polymorphisms among nonwhites. Additionally, prior to age 50, Blacks have a higher incidence of HF compared to whites. It is thought that this is due to a higher prevalence of hypertension, diabetes mellitus, and low socioeconomic status. Women tend to experience symptoms of HF that differ from men and despite making up 50% of the American population diagnosed with HF, women are underrepresented in trials evaluating HF therapy. The statement points to several interventions to address these disparities including: "developing a better understanding of the potential impact of SDOH on HF care; integrating the assessment and data collection related to SDOH for patients with HF into routine care, similar to other cardiac risk factors; designing and implementing interprofessional care teams that maximize patient access to varied perspectives and skill sets, which will facilitate self-care and navigation across the healthcare system; and increasing research examining the SDOH profile of patients with HF and the interventions that can be most beneficial in improving the health outcomes of patients with HF" (White-Williams, et al., 2020).

According to a 2023 guideline on acute mechanical circulatory support from the International Society for Heart and Lung Transplantation and Heart Failure Society of America, health equity considerations are critical in the application of acute mechanical circulatory support (MCS), particularly for women and racial or ethnic minorities. The guideline highlights that women, Asian/Pacific Islanders, and individuals over age 75 demonstrate a higher incidence of cardiogenic shock (CS) secondary to acute myocardial infarction (AMI). Specifically, registry data show that women are disproportionately affected by AMI-CS, yet they are less likely to receive early coronary revascularization and less likely to receive intra-aortic balloon pump (IABP) support compared to men. For example, IABP use was reported in 43% of women versus 55% of men with STEMI-CS. Similarly, African American patients were less likely to receive early mechanical revascularization and IABP support, with IABP use documented in 47.3% of African American patients versus 49.9% of White patients ($P < 0.001$). Furthermore, Hispanic patients had the highest in-hospital mortality among racial groups. These disparities underscore the need for equitable access to MCS-capable centers, inclusive clinical trial enrollment, and tailored device deployment strategies that account for anatomical and socioeconomic differences (Bernhardt, et al., 2023).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Ventricular Assist Devices (20.9.1)	10/30/2013
NCD	National	Artificial Hearts and Related Devices (20.9)	10/30/2013
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

FDA Approved/Cleared Devices

Implantable Ventricular Assist Devices:

Device or Product	Identifier	Manufacturer
CentriMag™ Blood Pump	P170038	Abbott Medical
Centrimag® Right Ventricular Assist System (RVAS)	H070004	Abbott Medical
Levitronix Centrimag® Extracorporeal Blood Pumping System, Model L-100	K020271	Levitronix LLC.
HeartWare® Ventricular Assist System	P100047	Medtronic
Thoratec Heartmate II Left Ventricular Assist System	P060040	Abbott Medical
HeartMate 3™ Left Ventricular Assist System	P160054	Abbott Medical
Levitronix Pedimag Blood Pump	K090051	Levitronix LLC
Abiomed AB5000 Circulatory Support System	P900023	Abiomed Cardiovascular, Inc.

*FDA product codes: DSQ, KFM, PCK, OJE

Pediatric Implantable Ventricular Assist Devices (VADs)

HeartAssist® – 5 Pediatric VAD (DeBakey VAD Child Ventricular Assist Device System)	H030003	Reliantheart Inc.
EXCOR® Pediatric Ventricular Assist Device	P160035	Berlin Heart Inc.

*FDA product codes: DSQ, PCK

Percutaneous Ventricular Assist Devices (VADs)

Device or Product	Identifier	Manufacturer
TandemHeart PTVA System	K110493	CardiacAssist, Inc
Impella Recover LP 2.5 Percutaneous Cardiac Support System	K063723	Abiomed, Inc.
Impella 5.0 Catheter Family	K083111	Abiomed, Inc.
Impella RP System	P170011	Abiomed, Inc.
The Impella® Ventricular Support Systems	P140003	Abiomed, Inc.

*FDA product codes: KFM, OZD, PYX, DWA

Total Artificial Heart

Device or Product	Identifier	Manufacturer
Syncardia Temporary Total Artificial Heart (TAH-T)	P030011	Syncardia Systems, LLC
Syncardia Freedom® Driver System	P030011	Syncardia Systems, LLC

*FDA product codes: LOZ

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

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Revision Details

Type of Revision	Summary of Changes	Date

Annual Review	• Revised policy statement for:
	  ○ Implantable VADs
	  ○ Pediatric implantable VADs
	  ○ Percutaneous VADs
	  ○ Total artificial heart
		12/15/2025

Focused Review/Annual Review	• Added a not medically necessary policy statement for the SynCardia Freedom Driver System.	1/15/2025
Annual Review	• Changed contraindication verbiage from "malignancy that is expected to significantly limit future survival" to "incurable systemic malignancy".	12/15/2023

	• Removed "a pattern of demonstrated noncompliance… which would place a VAD at serious risk of failure" from the list of contraindications. • Reorganized policy statements for percutaneous VADs. • Removed the statement pertaining to VADs used as part of an ECMO circuit from the policy statements. • Removed the SynCardia Freedom Driver System from the experimental, investigational or unproven for any other indication policy statement.	

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