

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medicare Advantage Medical Policy #MA-210

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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Total Artificial Hearts

Based on review of available data, the Health Plan may consider total artificial hearts (TAHs) as a bridge to heart transplantation **eligible for coverage** when all of the following criteria are met:

- TAH is used in accordance with FDA approval; **AND**
- Individual has biventricular heart failure; **AND**
- There are no other reasonable medical or surgical treatment options; **AND**
- Ineligible for other univentricular or biventricular support devices; **AND**
- Currently listed as heart transplantation candidate **OR** is undergoing evaluation to determine candidacy for heart transplantation **AND** is not expected to survive until a donor heart can be obtained; **AND**
- Absence of any of the contraindications:
 - Chronic irreversible hepatic, renal, or respiratory failure
 - Active systemic infection
 - Coagulation disorders and inability to tolerate anticoagulation therapy.

Percutaneous Ventricular Assist Devices

Based on review of available data, the Health Plan may consider percutaneous ventricular assist devices (pVADs) for the treatment of cardiogenic shock **eligible for coverage** when all of the following criteria are met:

- pVAD is FDA approved; **AND**
- Request is for an adult individual (18 years or older); **AND**
- Acute myocardial infarction of less than 36 hours duration with one of the following findings:

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

- ST- segment elevation myocardial infarction (STEMI) with new onset ST-segment elevation; **OR**
- New onset ST segment depression or left bundle branch block (LBBB) and emergency angiography demonstrating acute proximal occlusion of coronary artery; **AND**
- Cardiogenic shock of less than 24 hours duration confirmed by hypotension and all of the following:
 - Systolic blood pressure less than 100 mmHg or ongoing vasopressor support, e.g., dopamine, norepinephrine or epinephrine; **AND**
 - End-organ hypoperfusion with arterial lactate greater than or equal to 2.5 mmol/L; **AND**
 - Left ventricle ejection fraction (LVEF) less than 45%; **AND**
- Absence of ANY one of the following:
 - Individual has been resuscitated from out-of-hospital cardiac arrest and remained comatose on arrival to the cardiac catheterization laboratory with persistent Glasgow coma scale less than 8 after return of spontaneous circulation;
Note: Cardiac arrest occurring in the ambulance or after arrival to the hospital is NOT an exclusion criterion.
 - Severe right ventricle failure by echocardiogram;
 - Shock duration greater than 24 hours;
 - Other causes of shock, e.g., hypovolemia, sepsis, pulmonary embolism, anaphylaxis;
 - Shock due to mechanical complication to myocardial infarction
 - Papillary muscle rupture
 - Rupture of ventricular septum or ventricular free wall;
 - Severe aortic valve regurgitation or stenosis;
 - Established diagnosis of severe peripheral arterial obstructive disease or abnormalities of the aorta that would preclude pVAD placement;
 - Presence of a mechanical aortic valve prosthesis;
 - Left ventricle thrombus;
 - Infective endocarditis.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers other applications total artificial hearts (TAHs) including, but not limited to, the use of TAHs as destination therapy to be **investigational**.*

The use of non-FDA-approved or cleared TAHs is considered to be **investigational**.*

Based on review of available data, the Health Plan considers percutaneous VADs for all other indications to be **investigational**.*

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Background/Overview

Heart Failure

According to a 2025 report from the American Heart Association and based on data collected from 2017 to 2020, roughly 6.7 million Americans ages 20 years or older had heart failure during that time frame. Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years). Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socioeconomic status.

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and had a reported survival rate of nearly 92% or transplants performed in 2022. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of artificial heart systems and percutaneous ventricular assist devices (pVADs) and have been U.S. Food and Drug Administration (FDA) approved through a Humanitarian Device Exemption, 510(k), or premarket approval regulatory pathway. This section discusses currently marketed devices.

FDA maintains a list of recent device recalls at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls>.

Total Artificial Heart

The total artificial heart (TAH) is a biventricular device that completely replaces the function of the diseased heart. An internal battery requires frequent recharging from an external power source. Many systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Currently the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 2). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006, but is no longer being marketed or in development.

Table 2. Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	PMA No.	Indication
SynCardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

Percutaneous Ventricular Assist Devices

Some circulatory assist devices are placed percutaneously (i.e., are not implanted). They may be referred to as percutaneous VADs (pVADs). Two different pVADs have been developed, the TandemHeart and the Impella device (Table 3).

In the TandemHeart System, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. LivaNova, the company that acquired CardiacAssist Inc. (the original developer of the TandemHeart), announced plans to wind down its Advanced Circulatory Support business, including the TandemHeart, in 2024. However, it is possible that some components, such as cannulas, may still be available for purchase.

The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. As of June 5, 2023, the FDA has issued a Class I recall for specific Impella 5.5 devices due to purge fluid leaks. On October 10, 2025, the FDA issued an alert on the automated Impella controller correction due to a cybersecurity issue.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Devices in which most of the system's components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Adverse events associated with pVAD include access site complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

Table 3. Available Percutaneous Ventricular Assist Devices

Device	Manufacturer	Approval Date	FDA Clearance	PMA, 510(k) No.	Indication
TandemHeart	Cardiac Assist (LivaNova)	Sep 2011	510(k)	K110493	Temporary left ventricular bypass of ≤6 h
Impella CP	Abiomed	Nov 2016	PMA	P140003	<ul style="list-style-type: none"> • Temporary (≤6 hours) ventricular support devices indicated for use during high-risk PCI • Temporary ventricular support for ≤4 days in cardiogenic shock
Impella 5.5	Abiomed	Nov 2016	PMA	P140003	Temporary ventricular support for ≤14 days in cardiogenic shock

FDA: U.S. Food and Drug Administration; PCI: percutaneous coronary intervention; PMA: premarket approval.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Description

A ventricular assist device (VAD) is mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed.

Summary of Evidence

Total Artificial Heart

For individuals who have end-stage heart failure who receive a total artificial heart (TAH) as a bridge to transplant, the evidence includes case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Percutaneous Ventricular Assist Device

For individuals with infarct-related cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes three small, randomized trials that did not show a clinical benefit of microaxial flow pumps, registry studies that showed excess bleeding among patients who received a microaxial pump, and a more recent international, multicenter, randomized, open-label trial funded by the Danish Heart Foundation and Abiomed (DanGer Shock trial, NEJM 4/2024). DanGer Shock trial tested the hypothesis that routine use of a microaxial flow pump in addition to standard guideline-directed therapies in patients with STEMI-related cardiogenic shock results in a lower mortality than standard care alone. Patients with ST segment elevation myocardial infarction and cardiogenic shock were assigned to receive a microaxial flow pump (Impella CP) plus standard care or standard of care alone. The primary end point was death from any cause at 180 days (6 months). A composite safety end point was severe bleeding, limb ischemia, hemolysis, device failure, or worsening aortic regurgitation. From January 2013 through July 2023 a total of 1211 patients underwent screening. A total of 360 adult patients underwent randomization, 355 were included in final analysis (179 in the microaxial-flow-pump and 176 in the standard-care group). The median age of the patients was 67 years, and 79.2% were men. The median arterial lactate level was 4.5 mmol/L, the median systolic BP was 82 mm Hg, and the median LV EF was 25%. The trial was conducted in a more homogenous patient population (a mandatory elevation in arterial lactate level in the absence of a cardiac arrest led to the identification of a patient population with profound LV failure). In the microaxial-flow-

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

pump group, treatment was escalated to another mechanical circulatory support system in 28 patients (15.6%), and in the standard-care group in 37 patients (21%). Death from any cause occurred in 82 of 179 patients (45.8%) in the microaxial-flow-pump group and in 103 of 176 patients (58.5%) in the standard-care group (hazard ratio, 0.74; 95% confidence interval 0.55 to 0.99; P=0.04). The number needed to treat to avoid 1 death was 8. A composite safety end-point event occurred in 43 patients (24.0%) in the microaxial-flow-pump group and in 11 patients (6.2%) in the standard-care group (relative risk, 4.74; 95% CI, 2.36 to 9.55). In the microaxial-flow-pump group, the number needed to harm was 6. The relative risk (pump group vs. standard-care group) of moderate or severe bleeding was 2.06, of limb ischemia 5.15, and of sepsis with a positive blood culture 2.79. Renal-replacement therapy was administered to 75 patients (41.9%) in the pump group and to 47 patients (26.7%) in the standard-care group (relative risk, 1.98; 95% CI, 1.27 to 3.09). This considerably higher use of renal-replacement therapy is higher than that observed in the extracorporeal life support trial (ECLS-SHOCK trial). Authors noted that it remains a priority to address the prevention of serious adverse events that occur as a result of treatment with a microaxial flow pump. Trial limitations include strict inclusion and exclusion criteria; the results cannot be extrapolated to patients who remain comatose after cardiac arrest, patients without ST-segment elevation myocardial infarction, patients without an elevation in the arterial lactate level, and patients who have more prominent biventricular failure. The trial was conducted in a small number of centers in Denmark, Germany, and the United Kingdom, so results may differ in health care systems in other countries with more racial diversity. The trial was not blinded therefore authors could not exclude the possible effect on therapeutic decisions made by treating physicians. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Clinical input was obtained and supported coverage criteria that are based on the inclusion and exclusion criteria in the DanGer Shock trial, which is also consistent with the 2025 ACC/AHA Joint Committee on Clinical Practice Guidelines (Guideline for the management of patients with acute coronary syndromes).

For other individuals with cardiogenic shock who receive a percutaneous VAD (pVAD), the evidence includes RCTs, observational studies, and a systematic review. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD versus intra-aortic balloon pump (IABP) for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies and a long-term follow-up study were consistent with the RCT evidence. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cardiogenic shock refractory to IABP therapy who receive a pVAD, the evidence includes case series. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes RCTs, observational studies, and systematic reviews of these trials. Relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Randomized controlled trials, controlled and uncontrolled observational studies, and systematic reviews of these studies have generally not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures.

The PROTECT II trial (10/2012) led to the FDA approval of Impella as a temporary support for high-risk percutaneous cardiac interventions. Study included participants with PCI on an unprotected left main or last patent coronary vessel with LVEF $\leq 35\%$, or PCI for 3 vessel disease with LVEF $\leq 30\%$, and excluded patients with myocardial infarction, LV thrombus, PLT count $\leq 75,000/\text{mm}^3$, creatinine $\geq 4 \text{ mg/dL}$, or severe PVD precluding passage of the catheter. The primary endpoint of 30-day MAE in the PROTECT II study occurred in 34.3% of the per protocol (PP) patients in the Impella 2.5 arm compared with 42.2% of PP patients in the IABP arm ($P=0.092$). This study had important limitations. Because of the determination of futility, only 69% (452) of the planned enrollment occurred. A significant learning curve occurred in this trial with improvement in safety for Impella-supported patients in the last half of the trial. The trial did not enroll the number of patients it was powered for, therefore definitive statements concerning the primary end point are speculative. The trial could not be blinded of the presence of Impella support which led to a greater and more aggressive use of rotational atherectomy, and the differences confounded the analysis. Because the difference in 30-day major adverse events did not reach statistical significance for the entire study, the analysis of 90-day events remains exploratory.

Restore EF study (8/2022) was largest to date study looking at LV EF changes 30 days after high-risk PCI. It was an observational nonrandomized multicenter retrospective analysis of prospectively collected observational data set to assess 90-day LVEF in patients who survived with no additional procedure prior to 90-day assessment. 36 out of 495 screened patients (7.3%) who died before day 60 were excluded from assessment; 406 patients were evaluated. The study reported 30-day mortality of 6.9% (all screened patients), increasing to 9.5% at 180 days. Authors concluded that in an ideal cohort there is a signal that high-risk PCI affords improvement in 90-day LV EF (from median 35% to 45% with $P<.0001$, most pronounced in those with a baseline LVEF $\leq 20\%$, no change in patients with LVEF $> 45\%$ at baseline) along with significant relief of angina and heart failure symptoms, and that this hypothesis-generating finding merits assessment in large studies and randomized controlled trials. Important limitations include the lack of a comparator, investigator-reported data with no angiographic or echocardiographic core lab, or independent clinical events committee adjudication, and unknown impact on LVEF from optimal heart failure medical therapy (data on medications were not collected). A significant number of patients (61.8%) who were included in the final study population did not undergo 90-day follow-up LVEF assessment (due to patients missing appointment or physician not ordering LVEF assessment).

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

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The PROTECT III study was sponsored by Abiomed. It was a prospective, single-arm, FDA post-marketing approval (PMA) study of Impella 2.5[®]‡ and Impella CP[®]‡ in high-risk PCI. Trial included 898 patients enrolled at 45 sites in the United States between 3/2017 and 7/2019. Using cVAD registry database data, PROTECT III demonstrates a reduction in the primary endpoint of death, stroke, myocardial infarction and repeat procedures at 90 days with Impella-supported protected PCI, compared to PROTECT II.

Impella-supported PCI in high-risk patients with complex coronary artery disease and reduced LV function trial sponsored by Abiomed (the PROTECT IV trial, NCT04763200) is currently recruiting participants. It is an on-label, prospective, multi-center randomized controlled trial that is designed to provide the level of clinical evidence needed to achieve a global class I guideline recommendation (a strong recommendation, indicating that intervention is effective and should be performed in most patients in most circumstances) for Impella in high-risk PCI. The purpose of this study is to assess if using the Impella[®]‡ CP (or Impella[®] 2.5)‡ device during high-risk PCI in patients with reduced left-sided heart function will result in an improvement in symptoms, heart function and health outcomes after a PCI, compared to the current standard of care. Inclusion criteria: adult patients (18-90 years of age) with LVEF \leq 40% in setting of chronic coronary syndrome or NSTEMI, or STEMI \geq 24 hours and $<$ 30 days after symptom onset and LVEF \leq 30%, and need of complex PCI (triple vessel disease, left main disease, ostial LAD and ostial LCX disease, or intervention of the last remaining vessel). Estimated study completion is 10/2027.

There is a lack of large-scale, high-quality RCTs demonstrating clear clinical benefits in the use of any of the mechanical circulatory support (MCS) devices during high-risk PCI. European Society of Cardiology guidelines did not make specific recommendations on the use of MCS during revascularization while the American College of Cardiology made only a class IIb recommendation (weak recommendation for which it is unknown whether benefit will outweigh the risk) for the use of hemodynamic support device as an adjunct to complex PCI for selected high-risk patients to prevent hemodynamic compromise. Ongoing and future research will shed light on unanswered questions including those around the definition of complex, high-risk and indicated PCI, patient selection, device selection, evaluation of new devices and timing of support initiation.

Additionally, 2 nonrandomized studies have compared ventricular tachycardia (VT) ablation with pVAD or IABP. Both studies demonstrated that patients who had pVAD support spent less time in unstable VT than patients without pVAD support. However, the current evidence does not support conclusions about the use of pVAD for VT ablation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Thoracic Surgery et al

In 2020, the American Association for Thoracic Surgery and the International Society for Heart and Lung Transplantation published guidelines on selected topics in mechanical circulatory support (MCS), including recommendations on the use of pVADs (Table 4). The guideline authors noted, "Compared with IABP [intraaortic balloon pump], contemporary percutaneous circulatory support devices provide a significant increase in cardiac index and mean arterial pressure; however, reported 30-day outcomes are similar."

Table 4. 2020 Guidelines on Mechanical Circulatory Support

Recommendation	COE	LOE
"Percutaneous LV to aorta pumps of appropriate size should be considered for cardiogenic shock from primary LV failure."	IIA	B

COE: class of evidence; LOE: level of evidence; LV: left ventricular.

American College of Cardiology Foundation et al

In 2017, the American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA. Left ventricular assist device was 1 of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after guideline-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then a left ventricular assist device would be an additional treatment option. The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged. The American College of Cardiology Foundation and AHA (2013) released guidelines for the management of heart failure that included recommendations related to the use of MCS, including both durable and nondurable MCS devices. The guidelines categorized pVADs and extracorporeal ventricular assist devices (VADs) as nondurable MCS devices. Since the 2017 update, these guidelines have been updated regularly, with the most recent update occurring in 2022. Table 5 provides recommendations on MCS devices from the most recently updated guideline iteration.

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Table 5. AHA/ACC/HFSA Guidelines on Mechanical Circulatory Support

Recommendation	COE ^a	LOE ^b
"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, QOL, and survival."	I	A
"In select patients with advanced HFrEF who have NYHA class IV symptoms despite GDMT, durable MCS can be beneficial to improve symptoms, improve functional class, and reduce mortality."	IIA	B-R
"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'"	IIA	B-NR

ACC: American College of Cardiology; AHA: American Heart Association; COE: class of evidence; GDMT: guideline-directed medical therapy; HFrEF: heart failure with reduced ejection fraction; HFSA: Heart Failure Society of America; LOE: level of evidence; LVAD: left ventricular assist device; MCS: mechanical circulatory support; NYHA: New York Heart Association; QOL: quality of life; RCT: randomized controlled trial.

^aI: Strong; IIa: Moderate.
^bA: high quality evidence from more than 1 RCT; B-R: Moderate-quality evidence from 1 or more RCTs; B-NR: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies.

2025 ACC/AHA/ACEP/ NAEMSP/ SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines (based on a comprehensive literature search from July 2023 to April 2024) included grade 2a recommendation (a moderate recommendation for which benefit most likely outweighs the risk): “In selected patients with STEMI and severe or refractory cardiogenic shock, insertion of a microaxial intravascular flow pump is reasonable to reduce death.” Based on the results of the DanGer-SHOCK trial, “use of a microaxial flow pump is reasonable to reduce mortality in patients with STEMI and cardiogenic shock who have clinical features consistent with the inclusion criteria of the DanGer-SHOCK trial. In particular, patients with STEMI who present with SCAI shock stages C, D, or E, who are noncomatose and have adequate peripheral vasculature to accommodate large-bore access are reasonable candidates for the microaxial flow pump.”

One of the recommendations for mechanical complications of ACS is related to mechanical circulatory support (MCS) devices (2a): “In patients with a mechanical complication of ACS, short-term MCS devices are reasonable for hemodynamic stabilization as a bridge to surgery.” It is noted that no RCTs have evaluated the role of MCS devices in improving clinical outcomes in the setting of mechanical complications. In patients with ventricular septal rupture, the use of an IABP has been

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

shown to reduce left-to-right shunting and improve hemodynamics in patients with and without cardiogenic shock. Favorable hemodynamic effects with IABP are also noted with acute ischemic mitral regurgitation.”

American Heart Association

In 2012, the AHA published recommendations for the use of MCS. These guidelines defined nondurable MCS as IABPs, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 6 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 6. 2012 Guidelines on Mechanical Circulatory Support

Recommendation	COE	LOE
"MCS for BTT indication should be considered for transplant-eligible patients with end-stage HF who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation."	I	B
"Implantation of MCS in patients before the development of advanced HF ... is associated with better outcomes. Therefore, early referral of HF patients is reasonable."	IIA	B
"MCS with a durable, implantable device for permanent therapy or 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."	I	B
"Elective rather than urgent implantation of DT can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies."	IIA	C
"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." "These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF."	IIA I	C C
"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."	IIA	B

BTT: bridge to transplant; COE: class of evidence; DT: destination therapy; HF: heart failure; LOE: level of evidence; MCS: mechanical circulatory support.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

International Society for Heart and Lung Transplantation

The International Society for Heart and Lung Transplantation and the Heart Failure Society of America released a guideline on acute MCS in 2023. The guideline focuses on timing, patient and device selection of acute MCS, and periprocedural and postprocedural care for cardiogenic and pulmonary shock. They provide specific recommendations depending on which MCS device is chosen. Table 7 summarizes relevant recommendations for timing of acute MCS made in the guidelines. Additional recommendations related to specific devices is related to procedural considerations.

Table 7. ISHLT/HFSA Guideline on Acute Mechanical Circulatory Support

Recommendation	COR	LOE
"Acute MCS should be initiated as soon as possible in patients with CS who fail to stabilize or continue to deteriorate despite initial interventions."	I	B
"The use of acute MCS should be considered in patients with multiorgan failure to allow successful optimization of clinical status and neurologic assessment before placement of durable MCS or organ transplantation."	II	C

COR: class of recommendation; CS: cardiogenic shock; HFSA: Heart Failure Society of America; ISHLT: International Society for Heart and Lung Transplantation; LOE: level of evidence; MCS: mechanical circulatory support

Society for Cardiovascular Angiography and Interventions et al

In 2015, the Society for Cardiovascular Angiography and Interventions, the Heart Failure Society of America, the Society of Thoracic Surgeons, and the American College of Cardiology published a joint clinical expert consensus statement on the use of percutaneous MCS devices in cardiovascular care. This statement addressed IABPs, left atrial-to-aorta assist device (eg, TandemHeart), left ventricle-to-aorta assist devices (eg, Impella), extracorporeal membrane oxygenation, and methods of right-sided support. Specific recommendations were not made, but the statement reviews the use of MCS in patients undergoing high-risk percutaneous intervention, those with cardiogenic shock, and those with acute decompensated heart failure.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for VADs. The NCD mandates coverage for VADs for the following indications:

- For support of blood circulation in the post cardiectomy setting, defined as the period following open-heart surgery.
 - If the VAD has U.S. Food and Drug Administration (FDA) approval for that purpose and are used according to the FDA-labeled indication

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

- For short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for patients who meet the following criteria:
 - Have New York Heart Association (NYHA) Class IV heart failure; and
 - Have a left ventricular ejection fraction (LVEF) $\leq 25\%$; and
 - Are inotrope dependent

OR

have a cardiac index < 2.2 L/min/m², while not on inotropes, and also meet 1 of the following:

- Are on optimal medical management, based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; OR
- Have advanced heart failure for at least 14 days and are dependent on an IABP or similar temporary mechanical circulatory support for at least 7 days.

"Beneficiaries receiving VADs for DT [destination therapy] must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience.... The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD."

"Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services."

Effective December 1, 2020, Artificial Hearts has been removed from the NCD Manual. Coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors.

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Medical Policy #MA-210

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Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

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Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

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Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

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04/21/2026 Utilization Management Committee review/approval. New policy.

Next Scheduled Review Date: 04/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33927, 33928, 33929, 33990, 33991, 33992, 33993, 33995, 33997
HCPCS	L8698, Q0477, Q0478, Q0479
ICD-10 Diagnosis	I21.01 -I21.02, I21.11-I21.19, I21.21-I21.29, I21.3, I21.4, I21.9, I22.0-I22.9, R57.0, T81.11XA-T81.11XS

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the Health Plan’s Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Total Artificial Hearts and Percutaneous Ventricular Assist Devices

Medical Policy #MA-210

Original Effective Date: 07/01/2026

Current Effective Date: 07/01/2026

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: <https://www.cms.gov/medicare-coverage-database/search.aspx>. You may wish to review the Guide to the MCD Search here: <https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx>.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®

InterQual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.