Clinical Policy Title: Ventricular assist devices and total artificial heart

Clinical Policy Number: CCP.1250

Effective Date: October 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: August 1, 2018
Next Review Date: August 2019

Related policies:
CCP.1034  Heart transplants
CCP.1287  Cardiac rehabilitation
CCP.1314  Bloodless heart transplant
CCP.1161  External counterpulsation therapy

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of implanted, percutaneous, or extracorporeal ventricular assist devices and total artificial hearts to be clinically proven and, therefore, medically necessary: (1) when used in accordance with their U. S. Food and Drug Administration-labeled indication(s) and intended purpose(s); (2) when performed at a facility that has received certification by the Joint Commission under the Disease Specific Certification Program for ventricular assist devices, is a Medicare-approved heart transplantation facility, or is a facility with a United Network for Organ Sharing-approved heart transplantation program; (3) any of the following indications (Ponikowski, 2016; Feldman 2013; Yancy, 2013; Peura, 2012; Hunt, 2009):

- Ventricular assist devices:
  - As a bridge to transplantation for members with all of the following criteria:
    - Age five years or older.
    - Candidates for heart transplantation (See CP# 04.02.05 [changed to CCP.1034] Heart transplants) and whose imminent survival is in jeopardy without
mechanical circulatory support; or who will be evaluated for heart transplantation after a period of multi-organ improvement.

- Severe isolated left ventricular or biventricular dysfunction.

- As destination therapy to provide permanent mechanical circulatory support for members who meet all of the following criteria:
  - Not a candidate for heart transplantation at the time of ventricular assist device implantation.
  - New York Heart Association Class IV heart failure and one of the following:
    - Symptoms that failed to respond to guideline-directed optimal medical therapy (including beta-blockers and angiotensin converting enzyme inhibitors, if tolerated) for 45 of the last 60 days.
    - Received > 14 days of support with intra-aortic balloon pump.
    - Dependent on intravenous inotropic agents with two failed weaning attempts.
    - Left ventricular ejection fraction < 25 percent.
    - Demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless member is intra-aortic balloon pump- or intravenous inotrope-dependent, or is physically unable to perform the test.
  - As a bridge to recovery for the temporary mechanical circulatory support in patients with either:
    - Acute, potentially reversible, heart failure due to cardiogenic shock or myocarditis.
    - Post-cardiotomy who are unable to be weaned off cardiopulmonary bypass.

- Total artificial heart as a bridge to transplantation for members who meet all of the following criteria:
  - Biventricular failure.
  - Not expected to survive until a donor heart can be obtained.
  - No other surgical or medical treatment options.
  - Ineligible for univentricular or biventricular support devices.
  - Candidate for heart transplantation or is undergoing evaluation to determine candidacy for heart transplantation.
  - Receiving maximal medical therapy including intravenous inotropic support.

- Percutaneous ventricular assist device as a bridge to recovery and only when external counterpulsation (intra-aortic balloon pump) is not expected to be sufficient for either life-threatening indication (Rihal, 2015):
  - Cardiogenic shock.
  - Severe decompensated heart failure with threatening multi-organ failure.

- Implantable pediatric ventricular assist devices as a bridge to transplantation when either criterion is met (Kirk, 2014):
- Members age 5 years or older with end-stage left ventricular failure or another type of ventricular failure (e.g., the anatomic absence of a left ventricle) that requires temporary mechanical circulatory support.
- Members younger than age 5 years, requests will be considered on an individual basis upon review by a Company Medical Director.

For Medicare members only:

AmeriHealth Caritas considers the use of ventricular assist devices and total artificial heart to be medically necessary when use in accordance with the following National Coverage Determinations, Local Coverage Determinations, and Local Coverage Articles:

- 20.9 Artificial Hearts and Related Devices.
- 20.9.1 Ventricular Assist Devices.
- A53986 Percutaneous Ventricular Assist Device.
- A53988 Percutaneous Ventricular Assist Device.
- A54910 Ventricular Assist Device (VAD) Supply or Accessory.

These policies do not address coverage of ventricular assist devices for right ventricular support, biventricular support or use in beneficiaries under age 18 years with complex congenital heart disease or in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for ventricular assist devices in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

Limitations:

All other uses of a ventricular assist device or total artificial heart are not medically necessary.

Absolute contraindications for ventricular assist devices and total artificial hearts when used as bridge to transplantation include conditions that would generally exclude patients for heart transplantation, including, but not limited to (Rihal, 2015; Yancy, 2013; Peura, 2012:

- Chronic irreversible hepatic or respiratory failure.
- Irreversible kidney failure unless bridge to heart–kidney transplantation is considered.
- Active systemic infection or prolonged intubation.
- Coagulation disorders.
- Irreversible kidney failure unless bridge to heart–kidney transplantation is considered.
- Insufficient space in the thorax and/or abdominal cavity for the device (e.g., body surface area < 1.7 m², or distance between the sternum and 10th anterior vertebral body measured by computed tomography < 10 cm).
- Structural heart disease that prohibits or may interfere with a successful implantation (e.g., uncorrected valvular disease).
Underlying coagulopathy, either an international normalized ratio < 2.5 or a platelet count < 50,000. A contraindication to anticoagulation is a contraindication to mechanical circulatory support in most situations.

Relative contraindications include, but are not limited to (Ponikowski, 2016; Peura, 2012):

- Age > 80 years for destination therapy.
- Obesity > 40 kg/m² or malnutrition.
- Musculoskeletal disease that impairs rehabilitation.
- Untreated malignancy.
- Severe peripheral vascular disease.
- Active substance abuse.
- Impaired cognitive function.
- Unmanaged psychiatric disorder.
- Inadequate psychosocial support.

Ventricular assist device replacement supplies, as defined by the coding table in this policy, for use in the outpatient setting are eligible for separate reimbursement when the member meets the medical necessity criteria for a ventricular assist device that has been U.S. Food and Drug Administration-approved for use in the outpatient setting.

**Alternative covered services:**

- Cardiac rehabilitation.
- Pharmacologic therapy, including but not limited to: Angiotensin-Converting Enzyme Inhibitors; Angiotensin II Receptor Blockers (or Inhibitors); Angiotensin-Receptor Neprilysin Inhibitors; If Channel Blocker (or inhibitor); Beta Blockers; Aldosterone Antagonists; Hydralazine and isosorbide dinitrate (specifically benefits African Americans with heart failure); diuretics; digoxin; statins; and anticoagulants.
- Continuous intravenous inotropic infusion.
- Extracorporeal membrane oxygenation.
- Percutaneous coronary intervention.
- Intra-aortic balloon pump.
- Cardiac resynchronization (implantable cardioverter-defibrillator; cardiac resynchronization therapy).
- Corrective surgery (e.g., coronary artery bypass or valve replacement).
- Heart transplantation.

**Background**

Heart failure is a complex clinical syndrome resulting from any structural or functional impairment of ventricular filling or ejection of blood that fails to meet the body’s needs (Yancy, 2013). Disorders of the pericardium, myocardium, endocardium, heart valves, great vessels, or certain metabolic abnormalities can
cause heart failure and lead to episodes of arrhythmia, increasing pump failure, and premature death. Dyspnea and fatigue are the principal symptoms of heart failure; infants may also present with poor feeding, poor growth, excessive sweating, or even low blood pressure.

The class and type of heart failure are important considerations for managing patients with heart failure (American Heart Association, 2015). Most patients with heart failure have symptoms due to left ventricular impairment. Several validated classification systems are available to grade the severity of heart failure, including: the four-stage New York Heart Association functional classification; the American College of Cardiology/American Heart Association staging system; the European Society of Cardiology (European Society of Cardiology) system; and the Ross Classification System for infants and younger children (Rosenthal, 2004). The Interagency Registry for Mechanically Assisted Circulatory Support (2018), which acquires data on patients supported with U.S. Food and Drug Administration-approved mechanical circulatory support devices, further stratifies patients with advanced heart failure into seven clinical profiles by their signs and symptoms (See Appendix).

A subset of patients with chronic heart failure will continue to progress and develop persistently severe symptoms despite maximum guideline-directed medical therapy. Patients with advanced heart failure typically have symptoms at rest or with minimal exertion and cannot perform many activities of daily living. They are usually classified as American College of Cardiology/American Heart Association stage D or New York Heart Association Class IV and have clinically significant circulatory compromise (see Appendix).

**Mechanical circulatory support:**

Advanced heart failure is a debilitating condition for which heart transplantation offers the best treatment option. However, the supply of donor hearts is diminishing, and demand greatly exceeds supply. The shortage of donor hearts has encouraged the development of artificial mechanical devices that can assist or replace the function of the failing heart. A ventricular assist device is an electromechanical pump attached to the native heart and vessels to augment cardiac output. It is designed to partially or completely assist the ventricles of the native heart. A total artificial heart is attached to the pulmonary artery and aorta; it is designed to completely replace cardiac function and generally requires the removal of the patient's heart.

Surgically-placed ventricular assist devices are categorized by the implant location (implanted in the thorax or abdomen versus extracorporeal), flow characteristic (pulsatile versus continuous), pump mechanism (volume displacement, axial, or centrifugal), and the ventricle(s) supported (left, right, or biventricular). Percutaneous ventricular assist devices differ from other types of ventricular assist devices by using cardiac catheterization for placement, rather than open chest surgery, and a trans-septal approach to the left ventricle, which avoids potential difficulties in crossing the aortic valve.

The U.S. Food and Drug Administration (2018a, b, and c) has approved several ventricular assist devices/total artificial heart for specific clinical uses in adult and pediatric populations. Ventricular assist devices may be necessary for short-term (days to weeks), intermediate-term, or long-term (months to years) use. Ventricular assist devices for short-term use are inserted surgically or percutaneously to facilitate cardiac catheterization procedures as a bridge to recovery. Devices for intermediate and long-
term use are surgically implanted as intracorporeal devices or as extracorporeal devices as bridge to transplantation or destination therapy.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on June 15, 2018. Search terms were: “Heart-assist devices” (MeSH), “Heart, artificial” (MeSH), and free text terms “ventricular assist device” and “total artificial heart.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified six systematic reviews or other evidence syntheses (Neyt, 2016; Health Quality Ontario, 2016; Borisenko, 2014; Lang, 2014; Sutcliffe, 2013; Cheng, 2009), six professional guidelines (Ponikowski, 2016; Rihal, 2015; Feldman, 2013; Yancy, 2013; Peura, 2012; Rosenthal, 2004), and three cost-effectiveness analyses (Maini, 2014; Long, 2014; Sutcliffe, 2013) for this policy. The evidence consists of predominately retrospective case series and registry analyses. The highest quality evidence from randomized controlled trials and a majority of lower observational studies evaluated surgically-implanted left ventricular assist devices in adult populations (age 16 or older). The randomized controlled trials compared left ventricular assist devices to guideline-directed medical management as destination therapy, and percutaneous left ventricular assist devices versus intra-aortic balloon pumps for cardiogenic shock.

Ventricular assist devices are indicated for persons with end-stage heart failure with reduced ejection fraction (American College of Cardiology/American Heart Association stage D or New York Heart Association Class IV) who continue to progress and develop persistently severe symptoms despite maximum guideline-directed medical and device management. Most implanted ventricular assist devices were performed in persons classified at Interagency Registry for Mechanically Assisted Circulatory levels 1–3.
The primary goal of mechanical circulatory support, including ventricular assist devices, as a treatment strategy for patients presenting with advanced heart failure or cardiogenic shock is stabilizing a critically ill patient before making a decision regarding durable therapy. Newer generation implantable ventricular assist devices are smaller and more durable allowing for their use in myocardial recovery, possibly obviating the need for destination therapy. However, the distinction between the use of left ventricular assist devices as bridge to candidacy, when the therapeutic goal is to improve end-organ function in order to make an ineligible patient eligible for heart transplantation, bridge to transplantation, and destination therapy becomes somewhat arbitrary, as an increasing number of ventricular assist devices as bridge to candidacy will convert to destination therapy due to the limited number of heart donors.

The evidence suggests ventricular assist devices may facilitate myocardial recovery for individuals with reversible ventricular dysfunction, temporarily maintain circulation until transplant, or extend the life expectancy of the terminally ill. They can improve survival, quality of life, and functional status but are accompanied by a range of common complications, particularly with the newer continuous-flow left ventricular assist devices. The most common adverse events are bleeding, thromboembolism, infection, right ventricular failure requiring inotropic support, renal failure, and device failure. Late bleeding occurs mainly from gastro-intestinal origin.

The cost-effectiveness of left ventricular assist devices will depend on many factors including the clinical indication, availability of donor hearts for transplantation, device used, and patient and provider preferences (Long, 2014; Maini, 2014; Sutcliffe, 2013). While ventricular assist devices may improve survival in many cases, associated adverse events and small improvements in quality of life may limit their cost-effectiveness below conventionally held willingness-to-pay thresholds. Limited randomized controlled trials and other comparative studies make reliance on registry data and other database information critical to gauging long-term cost-effectiveness.

Few randomized comparative studies are available to guide patient or device selection for the patient requiring mechanical circulatory support beyond criteria established for U.S. Food and Drug Administration approval. In adult populations, some generalizations from consensus-based guidelines can be made:

- As bridge to transplantation, the efficacy of surgically-implanted left ventricular assist devices is demonstrated in numerous uncontrolled trials and trials comparing different ventricular assist devices among patients awaiting heart transplantation who have no other options for survival. Evidence for earlier ventricular assist device implantation in less severely ill patients (e.g., those not yet on inotropic support) requires further study.
- As bridge to transplantation, biventricular assist devices and total artificial hearts are available for patients with biventricular heart failure who meet criteria for heart transplantation and are at risk of imminent death. The effectiveness of temporary total artificial heart has been established only in patients with idiopathic and ischemic cardiomyopathies in a hospital setting.
- As destination therapy, left ventricular assist devices improve outcomes in patients who are not candidates for heart transplantation and can be considered for patients who are expected to be on a long-term waiting list for heart transplantation. Patient selection is based on enrollment criteria in
pivotal randomized controlled trials used to support U.S. Food and Drug Administration approval. Studies have not validated other preoperative variables to further refine patient selection and thereby improve patient outcomes. The safety and efficacy of biventricular assist devices or total artificial heart as destination therapy or total artificial heart used with a portable driver outside the hospital setting have not been established.

- As a bridge to candidacy, this concept has not been standardized, and the decision to label a given ventricular assist device implantation as bridge to candidacy (instead of either bridge to transplantation or destination therapy) may depend on several circumstances, such as the hemodynamic and general condition of the patient or donor availability. Observational data suggest the overall, long-term survival with left ventricular assist devices as bridge to candidacy is in-between that of bridge to transplantation and destination therapy, but results from randomized controlled trials are lacking.

- As a bridge to recovery, ventricular assist devices approved for temporary use (extracorporeal or percutaneous ventricular assist devices) in specific situations are available, but evidence of effectiveness is limited and conflicting. Guidelines vary in their enthusiasm for percutaneous ventricular assist devices, but most recommend them as an option in the settings of percutaneous coronary intervention and cardiogenic shock/heart failure post-cardiotomy in patients for whom established treatments provide or are likely to provide inadequate hemodynamic support. Extracorporeal ventricular assist devices provide temporary hemodynamic support for patients in acute heart failure or cardiogenic shock who otherwise faced an extremely high risk of mortality, but substantial uncertainty exists regarding the relative benefits versus alternatives (e.g., extracorporeal membrane oxygenation).

**Pediatrics:**

Ventricular assist devices have played an increasingly important role in the management of advanced heart failure in children (age 5 to 16 years). The predominant role of these devices has been as a bridge to transplantation with a demonstrated survival benefit based on multiple uncontrolled studies. Primary indications for mechanical circulatory support in pediatrics include heart failure related to congenital heart disease, cardiomyopathy and myocarditis, and cardiac allograft failure.

The most commonly used method of mechanical circulatory support in children is extracorporeal membrane oxygenation, and the only percutaneous device approved in the United States for short-term cardiac support in children is the intra-aortic balloon pump. Extracorporeal membrane oxygenation is able to provide complete circulatory support in a wide range of patients from newborns to adults both with and without congenital heart disease, but it is highly invasive and survival rates remain low at 40 to 50 percent.

As improvements in device design has allowed for lower pump volumes, there is interest in extending ventricular assist devices to high-risk populations (e.g., small infants and those with complex congenital heart disease) for whom the options for mechanical circulatory support are more limited. Ventricular assist devices as bridge to recovery and destination therapy are active areas of investigation in clinical trials and Pediatric Interagency Registry for Mechanical Circulatory Support (2018) analyses. Femoral vessel size limits
the use of current U.S. Food and Drug Administration-approved percutaneous ventricular assist devices in small children.

Policy updates:

In 2017, we added three Pediatric Interagency Registry for Mechanically-Assisted Circulatory Support data analyses (Blume, 2016; Rosenthal, 2016; Rossano, 2016) and one evidence-based guideline update from the International Society for Heart and Lung Transplantation (Kirk, 2014) that addressed mechanical circulatory support in pediatric populations. Two analyses reported on characteristics and outcomes of 200 patients with a median age of 11 years (range 11 days to 18 years) and total follow-up of 783 patient-months, who underwent 222 durable ventricular assist device implants (Blume, 2016; Rosenthal, 2016). Rosano et al analyzed a subset of 109 patients supported with continuous-flow ventricular assist devices at 35 hospitals.

The majority of durable ventricular assist device recipients had an underlying disease of cardiomyopathy, underwent previous cardiac surgery or extracorporeal membrane oxygenation, had an Interagency Registry for Mechanically Assisted Circulatory Level 1 or 2 at the time of implant, and was supported primarily with a left ventricular assist device alone. Pulsatile-flow devices were used in 45 percent of cases and continuous-flow devices in 55 percent.

Actuarial survival ranged from 81 percent to 86 percent at six months (Blume, 2016; Rosenthal, 2016). The most frequent adverse events were device malfunction, infection, neurologic dysfunction, and bleeding, and most adverse events were likely to occur in the first 30 days. The overall rate of early (within 90 days of implantation) and late adverse events was 86.3 events per 100 patient-months and 20.4 events per 100 patient-months, respectively, which are comparable to adult outcomes (Rosenthal, 2016). At six months, continuous-flow ventricular assist devices as bridge to transplantation appear to have outcomes similar to those of adults, suggesting an expanding role for these devices in pediatric populations (Rossano, 2016).

Further study is needed to understand the impact of varying patient and device characteristics on outcomes in pediatric patients with the goal of improving adverse event rates and survival. These results and the updated guideline are consistent with our current policy, and no policy changes are warranted.

In 2018, we added one registry outcome study that found ventricular-assist device as bridge to transplantation mitigates the severity of illness in pediatric patients who require heart transplantation. These results confirm the value of ventricular assist devices as a bridge to transplantation in pediatric populations, and no policy changes are warranted. Policy ID changed from CP# 04.02.07 to CCP.1250.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Sutcliffe (2018)</td>
<td>Key points:</td>
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<tr>
<td></td>
<td>• Registry analysis of 147 patients with pre-transplant ventricular assist device support (index cohort) compared to 630 patients without pre-transplant ventricular assist device</td>
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| device patients: A Pediatric Interagency Registry for Mechanically-Assisted Circulatory Support - Pediatric Heart Transplant Study linkage analysis | (Pediatric Heart Transplant Study; comparator cohort).  
- At implant, the index cohort was: Interagency Registry for Mechanically Assisted Circulatory Support Profile 1 in 33 (23%), Profile 2 in 89 (63%) and Profile 3 in 14 (10%) patients (see Appendix); older, larger, and less likely to have congenital heart disease ($P < .0001$); but greater requirements for inotrope and ventilator support and increased liver and renal dysfunction ($P < .0001$), both of which normalized at transplant after device support.  
- No between-cohort differences in 1-year post-transplant survival (96% vs 93%, $P = .3$), freedom from infection (81% vs 79%, $P = .9$) or freedom from rejection (71% vs 74%, $P = .87$). |
| Health Quality Ontario (2016) | Key points:  
- Overview of three systematic reviews and one observational study and three cost-effectiveness analyses (two from U.S. perspective) of adults with end-stage heart failure who were ineligible for heart transplantation (approximately 2,795 total patients, not clearly defined).  
- Low-to-moderate quality evidence suggests continuous-flow–left ventricular assist devices improved survival and quality of life and was more cost-effective than medical management. |
| Neyt (2016) for the Belgium Health Care Knowledge Centre | Key points:  
- Systematic review of four systematic reviews for adverse events, three randomized controlled trials (two published, one unpublished in progress) and five Interagency Registry for Mechanically Assisted Circulatory registry studies; patients with New York Heart Association class III/IV end-stage heart failure or cardiogenic shock.  
- Destination therapy (two randomized controlled trials, 329 total patients):  
  - Versus medical management, ventricular assist device improved survival and quality of life in patients with end-stage heart failure, particularly newer continuous-flow left ventricular assist devices.  
  - Adverse events: 8 to 100% early bleeding; 12 to 23% late bleeding mainly from gastro-intestinal origin; 8% and 11% ischemic and hemorrhagic stroke, respectively after two years; 20 to 49% local infection, 12 to 22% at the driveline, 20 to 36% sepsis; 5 to 25% right heart failure requiring inotropic support; 2.9% and 6.5% device failure rates at 12 and 24-months post-implantation, respectively.  
- As bridge to candidacy: no randomized controlled trials available, but not cost-effective, as increasing the number of left ventricular assist devices will convert to destination therapy since the number of heart donors is not increasing. |
| Ponikowski (2016) for the European Society of Cardiology | Key points:  
- Mechanical circulatory support indicated for patients with either chronic or acute heart failure who cannot be stabilized with medical therapy to unload the failing ventricle and maintain sufficient end-organ perfusion.  
- Majority of ventricular assist devices are done at Interagency Registry for Mechanically Assisted Circulatory levels 1–3, but earlier implantation in less severely ill patients, e.g., those not yet on inotropic support, may offer better outcomes than continuing on medical therapy based on a recent trial.  
- Bridge to destination therapy: extracorporeal, short-term mechanical circulatory support |
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<tr>
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<td>considered in refractory cardiogenic shock depending on patient age, comorbidities, and neurological function.</td>
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<td></td>
<td>• Bridge to candidacy: usually left ventricular assist device. For patients with active infection, severe renal, pulmonary or hepatic dysfunction or uncertain neurological status after cardiac arrest or due to cardiogenic shock.</td>
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<tr>
<td></td>
<td>• Bridge to transplantation: left ventricular assist device or biventricular assist device. Consider in patients with end-stage heart failure and reduced ejection fraction despite optimal medical and device therapy and who are eligible for heart transplantation, to improve symptoms and reduce the risk of heart failure hospitalization and premature death.</td>
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<td>• Bridge to recovery: typically left ventricular assist device for chronic end-stage heart failure; percutaneous mechanical circulatory support not proven or efficacious for cardiogenic shock.</td>
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<td></td>
<td>• Destination therapy: left ventricular assist device for heart transplantation-ineligible or long-term waiting list for heart transplantation. For patients with end-stage heart failure and reduced ejection fraction on optimal medical and device therapy to reduce the risk of premature death.</td>
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<td>Rihal (2015) for the Society for Cardiovascular Angiography and Interventions, The American College of Cardiology Foundation, The Heart Failure Society of America, And The Society for Thoracic Surgery</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Guideline for percutaneous mechanical circulatory support for advanced heart failure and cardiogenic shock</td>
<td>• Interagency Registry for Mechanically Assisted Circulatory 1 and 2 patients may be considered for temporary mechanical circulatory support as a bridge to recovery, surgical mechanical circulatory support, or heart transplantation.</td>
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<tr>
<td></td>
<td>• Percutaneous mechanical circulatory support offers superior hemodynamic support to pharmacologic therapy, particularly Impella and Tandem Heart devices.</td>
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<td>• Consider mechanical circulatory support for:</td>
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<td>• Cardiogenic shock, early placement if fail to stabilize or improve quickly after initial interventions.</td>
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<td></td>
<td>• Isolated acute right ventricular failure complicated by cardiogenic shock.</td>
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<td>• High-risk percutaneous coronary intervention, particularly if patient is inoperable or has severely decreased ejection fraction or elevated cardiac filling pressures.</td>
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<td>• Acute decompensated heart failure:</td>
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<td>• Percutaneous mechanical circulatory support for continued deterioration after initial interventions.</td>
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<td>• Mechanical circulatory support in candidates for surgically implanted ventricular assist devices or when rapid recovery is expected (e.g., fulminant myocarditis or stress-induced cardiomyopathy).</td>
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<td>• Inconclusive data regarding routine use of mechanical circulatory supports as adjunct to primary revascularization for large acute myocardial infarction to reduce reperfusion injury or infarct size.</td>
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<td>• Severe biventricular failure, using right- and left-sided percutaneous mechanical circulatory support, veno-arterial extracorporeal membrane oxygenation, or left ventricular assist device implantation with inotropic support.</td>
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<td>• Mechanical circulatory support may be more cost-effective for emergent support than surgical extracorporeal membrane oxygenation or ventricular assist device, and for elective use versus intra-aortic balloon pump.</td>
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<td>Borisenko (2014)</td>
<td><strong>Key points:</strong></td>
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<td>Right ventricular assist</td>
<td>• Systematic review and meta-analysis of 53 publications (999 total adult and pediatric</td>
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<td>device as bridge to transplantation, destination therapy, or bridge to recovery</td>
<td><strong>CentriMag</strong>&lt;br&gt;• Overall quality: Low. Predominately retrospective case series.&lt;br&gt;• Significant survival benefits to patients with cardiorespiratory failure due to:&lt;br&gt;  - Pre-cardiotomy cardiogenic shock 82% (95% confidence interval [CI] 70 to 92%).&lt;br&gt;  - Post-cardiac surgery cardiogenic shock 63% (95% CI 46 to 78%) in ventricular assist device.&lt;br&gt;  - Post-heart transplantation rejection or failure 62% (95% CI 46 to 76%).&lt;br&gt;  - Post-left ventricular assist device placement right ventricular failure 83% (95% CI 73 to 92%).&lt;br&gt;• Adverse event rates: bleeding on device support 28% (95% CI 23 to 32%); thrombosis 7% (95% CI 5 to 11%); hemolysis 3% (95% CI 1 to 6%), neurological complications 7% (95% CI 4 to 11%), infections 24% (95% CI 19 to 30%), renal complications 28% (95% CI 22 to 36%), and device failure 0.08% (95% CI 0.0 to 0.5, in two studies only).&lt;br&gt;• Adverse event rates are higher in pediatric populations than adults, but only bleeding and thrombosis rate differences were statistically significant between groups.&lt;br&gt;• Mean duration of support ranged 8.8 days for posttransplant graft failure indication to 25.0 days in precardiotomy indication. Total duration 1 to 146 days.</td>
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<tr>
<td>Kirk (2014) for the International Society for Heart and Lung Transplantation Guideline for management of pediatric heart failure</td>
<td><strong>Key points:</strong>&lt;br&gt;• Ventricular assist device as a bridge to transplantation if child is unable to be weaned from inotropic support and shows early, reversible dysfunction of ≥ one other major organ system (Class I, Level of evidence [level of evidence] C).&lt;br&gt;• Ventricular assist device as destination therapy provided a system is available that permits discharge to home with regular outpatient follow-up (Class IIb, level of evidence C).&lt;br&gt;• Extracorporeal membrane oxygenation or temporary ventricular assist device:&lt;br&gt;  - Bridge to recovery for isolated potentially reversible cause; if recovery does not occur, then transition to a ventricular assist device for bridge to transplantation or destination therapy (if child can receive a second-or third-generation ventricular assist device) (Class IIa, level of evidence C).&lt;br&gt;  - For resuscitation of end-organ function in cardiogenic shock with an irreversible underlying cause, rather than directly implanting a chronic ventricular assist device system (Class IIa, level of evidence C).&lt;br&gt;• Extracorporeal membrane oxygenation as bridge to recovery:&lt;br&gt;  - For emergency support in cardiac arrest or cardiogenic shock with pulmonary compromise (Class IIa, level of evidence C).&lt;br&gt;  - For neonates with univentricular circulation of a reversible cause (Class IIb, level of evidence C).&lt;br&gt;• Extracorporeal membrane oxygenation as bridge to transplantation for neonates with univentricular circulation based on anticipated waiting list times and donor scarcity (Class IIb, level of evidence B).&lt;br&gt;• Biventricular assist device if left ventricular assist device alone is inadequate; however, decision making is highly individualized, with no broadly useful risk-stratification scheme available (Class IIb, level of evidence C).&lt;br&gt;• Long-term ventricular assist device for neonate or older child with failed univentricular circulation, but associated with poor outcomes for neonates and moderate for older children. Class IIb, level of evidence B.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Yancy (2013) for the American College of Cardiology | - Long-term ventricular assist device for neonate with univentricular circulation after failure to wean from cardiopulmonary bypass after palliative surgery not routinely recommended due to associated poor outcomes Class III, level of evidence B.  
- Recovery protocol from chronic ventricular assist device can be considered if recovery of cardiac function is documented Class IIb, level of evidence C. |
| Land (2014) | **Key points:**  
- Best evidence synthesis of 13 case series (three animal studies, 10 retrospective cohort studies).  
- Improved hemodynamic stability during and after right ventricular assist device support: central venous pressure ($P = .005$), mean pulmonary artery pressures ($P < .01$), and increases in right ventricular cardiac output ($P < .05$), ejection fraction ($P < .05$), stroke work ($P < .05$), and pulmonary artery oxygen saturations ($P < .05$).  
- Complications included bleeding, thromboembolism and sepsis.  
- Higher mortality with percutaneous right ventricular assist device versus surgical right ventricular assist device (80% versus 44%). |
| Feldman (2013) for the International Society for Heart and Lung Transplantation (International Society for Heart and Lung Transplantation) Guidelines for mechanical circulatory support | **Key points:**  
- Candidates should have New York Heart Association functional class and Interagency Registry for Mechanically Assisted Circulatory support.  
- Management guided by individual clinicians and center-specific protocols.  
- Few randomized studies to guide patient selection and care of the mechanical circulatory support patient.  
- Short-term success depends on patient selection, surgical technique and post-operative management.  
- Long-term success depends on physician and patient engagement in device care and personal health. |
| Sutcliffe (2013) | **Key points:**  
- Systematic review of 40 single-arm prospective or retrospective case series (≥50 patients) of adults (age≥16 years) with advanced heart failure eligible for heart transplantation; 29 series studied HeartMate II.  
- No high-quality comparative empirical studies of ventricular assist devices as bridge to transplantation versus MM or as destination therapy versus bridge to transplantation.  
- Adverse events at 12 months: 4% to 27% bleeding requiring transfusion; 1.5% to 40% stroke; 3.3% to 48% infection; 1% to 14% device failure; 3% to 30% heart failure; 11% to 32% reoperation; and 3% to 53% renal failure.  
- Statistically significant improvements in quality of life and functional status reported in studies of two devices (HeartMate II and HeartWare). Variety of measures used.  
- Patients with advanced heart failure with existing vascular and renal function and whose quality of life and life expectancy are poor may accept a high risk of adverse events to achieve a better quality of life post-transplant. |
| Impella Recover RD CentriMag | **Key points:**  
- Mechanical circulatory support is beneficial in carefully selected patients with stage D... |
(refractory) heart failure with reduced ejection fraction as either bridge to transplantation or bridge to recovery (level of evidence: B [data derived from single randomized controlled trial or nonrandomized studies in select populations]).

- Nondurable mechanical circulatory support, including percutaneous and extracorporeal ventricular assist devices, is reasonable as a bridge to recovery or “bridge to decision” for carefully selected patients with heart failure with reduced ejection fraction with acute, profound hemodynamic compromise (level of evidence: B).
- Durable mechanical circulatory support as destination therapy is reasonable to prolong survival for carefully selected patients with stage D heart failure with reduced ejection fraction. (level of evidence: B).

Key points:

- Bridge to transplantation for patients who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving heart transplantation. (Class I; level of evidence B).
- Bridge to transplantation for patients whose heart transplantation ineligibility is solely to pulmonary hypertension related to heart failure alone (Class IIa; level of evidence B).
- Destination therapy for patients: 1) with advanced heart failure, high 1-year mortality resulting from heart failure and absence of other life-limiting organ dysfunction; 2) who are ineligible for heart transplantation (Class I; level of evidence B); and 3) pre-advanced heart failure early referral (Class IIa; level of evidence B).
- Elective rather than urgent implantation of destination therapy after optimal medical therapy for advanced heart failure patients who are failing medical, surgical and/or device therapies (Class IIa; level of evidence C).
- Bridge to recovery for hemodynamically compromised patients with heart failure with reversible end-organ dysfunction and/or relative contraindications to heart transplantation/durable mechanical circulatory support (Class IIa; level of evidence C).
- Bridge to destination therapy or bridge to recovery in cardiogenic shock when impossible to fully determine candidacy for heart transplantation to determine neurological recovery and to stabilize potentially reversible comorbidities.
- Extracorporeal devices as salvage support for patients in cardiogenic shock who otherwise faced an extremely high risk of mortality.
- Percutaneous mechanical circulatory support for temporary support during high-risk percutaneous coronary intervention in the cardiac catheterization laboratory and for post-cardiotomy heart failure and cardiogenic shock.
- Recommend using the device that is familiar to the team and can best serve the needs of the patient.

References

**Professional society guidelines/other:**


Peer-reviewed references:
About Heart Failure. American Heart Association website. 


Centers for Medicare & Medicaid Services National Coverage Determinations:

20.9 Artificial Hearts and Related Devices.

20.9.1 Ventricular Assist Devices.

Local Coverage Determinations:

A53986 Percutaneous Ventricular Assist Device.

A53988 Percutaneous Ventricular Assist Device.

A54910 Ventricular Assist Device (VAD) Supply or Accessory.

Commonly submitted codes
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>33945</td>
<td>Heart transplant, with are without recipient cardiectomy</td>
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<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
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<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
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<td>33979</td>
<td>Insertion of ventricular assist device; implantable intracorporeal, single ventricle</td>
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<td>33990</td>
<td>Insertion of ventricular assist device; percutaneous including radiological supervision and interpretation, arterial access only</td>
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<tr>
<td>33991</td>
<td>Insertion of ventricular assist device; percutaneous including radiological supervision and interpretation, both arterial and venous access, with transseptal puncture</td>
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<tr>
<th>ICD Code</th>
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<td>Biventricular heart failure</td>
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<td>No Applicable Codes</td>
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**Appendix**

New York Heart Association Functional Classification of Heart Failure (1994):

- **Class I.** No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
- **Class II.** Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- **Class III.** Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (~ up to 300 feet). Comfortable only at rest.
- **Class IV.** Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

American College of Cardiology Foundation/American Heart Association Stages of Heart Failure (Hunt, 2009):

- **Stage 1.** At high risk for heart failure but without structural heart disease or symptoms of heart failure.
- **Stage 2.** Structural heart disease but without signs or symptoms of heart failure.
- **Stage 3.** Structural heart disease with prior or current symptoms of heart failure.
- **Stage 4.** Refractory heart failure requiring specialized interventions. Unable to carry on any physical activity without symptoms of heart failure, or symptoms of heart failure at rest.
Interagency Registry for Mechanically Assisted Circulatory profiles for classifying patients with advanced heart failure at time of implant (2018):

Profile 1. **Critical cardiogenic shock**, “crash and burn.”

Profile 2. **Progressive decline**, on inotropic support or in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia or other intolerance.

Profile 3. **Stable but inotrope dependent**, or has a temporary circulatory support device after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal).

Profile 4. **Resting symptoms** describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living.

Profile 5. **Exertion intolerant** living predominantly within the house or housebound.

Profile 6. **Exertion limited**, comfortable at rest without evidence of fluid overload and able to do some mild activity but easily fatigued with any meaningful physical exertion, and likely to have had a hospitalization for heart failure within the past year.

Profile 7. **Advanced New York Heart Association Class III**, clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent.