Clinical Policy Title: Ventricular assist devices and total artificial heart

Clinical Policy Number: 04.02.07

Effective Date: October 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: July 20, 2016
Next Review Date: July 2017

Related policies:
- CP# 04.02.05 Heart transplant
- CP# 04.02.02 Cardiac rehabilitation

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s 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 Pennsylvania 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 Pennsylvania’s 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 Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of VADs and TAHs to be clinically proven and, therefore, medically necessary when used in accordance with their United States Food and Drug Administration (FDA)-labeled indication and intended purpose and when performed at a facility that has received VAD certification by the Joint Commission under the Disease Specific Certification Program for VADs, is a Medicare-approved heart transplantation (HT) facility, or is a facility with a United Network for Organ Sharing -approved HT program.

Medically necessary indications for VADs:
- As a bridge to transplantation (BTT) for members with all of the following criteria:
  - Age five years or older.
  - Candidates for HT (See CP# 04.02.05 Heart transplant) and whose imminent survival is in jeopardy without mechanical circulatory support (MCS); or who will be evaluated for HT after a period of multi-organ improvement.
  - Severe isolated left ventricular or biventricular dysfunction.
- As destination therapy (DT) to provide permanent MCS for members who meet all of the following criteria:
  - Not a candidate for HT at the time of VAD implantation.
New York Heart Association (NYHA) Class IV HF and one of the following:
- Symptoms that failed to respond to guideline-directed optimal medical therapy (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days.
- Received >14 days of support with intra-aortic balloon pump (IABP).
- Dependent on intravenous (IV) inotropic agents with two failed weaning attempts.
- Has a left ventricular ejection fraction (LVEF) <25 %.
- Has a demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless member is IABP- or IV inotrope-dependent, or is physically unable to perform the test.

- As a bridge to recovery (BTR) for the temporary MCS in patients with either:
  - Acute, potentially reversible, HF due to acute cardiogenic shock (CS) or acute myocarditis.
  - Post-cardiotomy who are unable to be weaned off cardiopulmonary bypass.

Medically necessary indications for TAH:
- As a BTT 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 HT or is undergoing evaluation to determine candidacy for HT.
  - Receiving maximal medical therapy including intravenous inotropic support.

Medically necessary indications for percutaneous VADs (pVADs):
- As a BTR and only when external counterpulsation (IABP) is not expected to be sufficient for the following life-threatening indications:
  - CS.
  - Severe decompensated HF with threatening multi-organ failure.

Medically necessary indications for implantable pediatric VADs:
- As a BTT when either of the following criteria are met:
  - Member over the age of 5 with end-stage left ventricular failure or another type of ventricular failure (e.g., the anatomic absence of a left ventricle) that requires temporary MCS.
  - Requests for VADs for those younger than the age 5 years will be considered on an individual basis upon review by a Company Medical Director.

For Medicare members only:

AmeriHealth Caritas Pennsylvania considers the use of VADs and TAH to be medically necessary when use in accordance with the following National Coverage Determinations (NCDs) and local coverage articles:

- 20.9 Artificial Hearts and Related Devices.
- 20.9.1 Ventricular Assist Devices.
- A52375 Category III CPT® Code Coverage.
- A53986 Percutaneous Ventricular Assist Device (South Carolina).
- A54910 Ventricular Assist Device (VAD) Supply or Accessory (Louisiana, Washington DC, Pennsylvania).

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

Limitations:

- All other uses of VADs or TAH are not medically necessary.
- Absolute contraindications for VADs and TAHs when used as BTT include conditions that would generally exclude patients for HT, including but not limited to:
  - 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.
  - Inadequate psychosocial support.
  - 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 (CT) < 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 MCS in most situations.
- Relative contraindications include, but are not limited to:
  - Age > 80 years for DT.
  - 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.
- VAD 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 VAD that has been FDA-approved for use in the outpatient setting.

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:
33990 - Insertion of ventricular assist device; percutaneous including radiological supervision and interpretation, arterial access only

33991 - Insertion of ventricular assist device; percutaneous including radiological supervision and interpretation, both arterial and venous access, with transeptal puncture

Alternative covered services:

- Cardiac rehabilitation.
- Pharmacologic therapy, including but not limited to: Angiotensin-Converting Enzyme (ACE) Inhibitors; Angiotensin II Receptor Blockers (or Inhibitors); Angiotensin-Receptor Neprilysin Inhibitors (ARNIs); L Channel Blocker (or inhibitor); Beta Blockers; Aldosterone Antagonists; Hydralazine and isosorbide dinitrate (specifically benefits African Americans with HF); diuretics; digoxin; statins; and anticoagulants.
- Continuous intravenous inotropic infusion.
- Extracorporeal membrane oxygenation (ECMO).
- Percutaneous coronary intervention (PCI).
- IABP.
- Cardiac resynchronization (implantable cardioverter-defibrillator [ICD]; cardiac resynchronization therapy [CRT]).
- Corrective surgery (e.g., coronary artery bypass or valve replacement).
- HT.

Background

HF 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 (American College of Cardiology/American Heart Association [ACC/AHA], 2013). Disorders of the pericardium, myocardium, endocardium, heart valves, great vessels or certain metabolic abnormalities can cause HF and lead to episodes of arrhythmia, increasing pump failure and premature death. Dyspnea and fatigue are the principal symptoms of HF; infants may also present with poor feeding, poor growth, excessive sweating or even low blood pressure. Most patients with HF have symptoms due to left ventricular (LV) impairment.

The class and type of HF are important considerations for managing patients with HF (AHA, 2015). The two types of ventricular failure are HF with preserved ejection fraction (HFrEF) and HF with reduced EF (HFrEF) (AHA, 2015). Several validated classification systems are available to grade the severity of HF, including: the four-stage NYHA functional classification; the ACC/AHA staging system; the 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 (INTERMACS), which acquires data on patients supported with FDA-approved MCS devices, further stratifies patients with advanced HF into seven clinical profiles by their signs and symptoms (INTERMACS, 2016; See Appendix).

A subset of patients with chronic HF will continue to progress and develop persistently severe symptoms despite maximum guideline-directed medical therapy. Patients with advanced HF typically have symptoms at rest or with minimal exertion and cannot perform many activities of daily living. They are...
usually classified as ACC/AHA stage D or NYHA Class IV and have clinically significant circulatory compromise (See Appendix).

**Treatment:**

Treatment depends on the cause, type and stage of HF. Treatment options in early stage HF address both causes and prevention of HF. As the disease progresses, more invasive options may be indicated; prognosis is poor in the absence of intervention (Yancy, 2013).

**MCS:**

Advanced HF is a debilitating condition for which HT 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 VAD 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 TAH 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 VADs 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 VADs (pVADs) differs from other types of VADs 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.

Both the VAD and TAH may be used as a bridge-to-HT (BTT) or as destination therapy (DT) in those who are not candidates for HT. The VAD is also used as a bridge-to-recovery (BTR) in patients with reversible conditions affecting cardiac output or as a bridge-to-candidacy (BTC) in whom candidacy for HT is unclear. Patients may be switched from one strategy to another depending on clinical progress and evolving patient preference.

FDA has approved several VADs/TAH for specific clinical uses in adult and pediatric populations (FDA, 2016a, 2016b and 2016c). VADs may be necessary for short-term (days to weeks) or intermediate and long-term (months to years) use. VADs for short-term use are inserted surgically or percutaneously to facilitate cardiac catheterization procedures as a BTR. Devices for intermediate and long-term use are surgically implanted as intracorporeal devices or as extracorporeal devices as BTT or DT.

**Searches**

AmeriHealth Caritas Pennsylvania 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 (CMS).

We conducted searches on June 21-22, 2016. Search terms were: "Heart-Assist Devices"[Mesh] OR "Heart, Artificial"[Mesh].
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 12 systematic reviews or other evidence syntheses, six professional guidelines and three cost-effectiveness analyses for this policy. The evidence consists of predominately retrospective case series and registry analyses. The highest quality evidence from randomized controlled trials (RCTs) and majority of lower observational studies evaluated surgically-implanted LVADs in adult populations (age 16 or older). The RCTs compared LVADs versus guideline-directed medical management as DT and pLVAD versus IABP for CS. VADs are indicated for persons with end-stage HFrEF (ACC/AHA stage D or NYHA Class IV) who continue to progress and develop persistently severe symptoms despite maximum guideline-directed medical and device management. Most implanted VADs were performed in persons classified at INTERMACS levels 1–3.

The primary goal of MCSs, including VADs, as a treatment strategy for patients presenting with advanced HF or CS is stabilizing a critically ill patient before making a decision regarding durable therapy. Newer generation implantable VADs are smaller and more durable allowing for their use in myocardial recovery, possibly obviating the need for DT. However, the distinction between the use of LVADs as bridge to candidacy (BTC), when the therapeutic goal is to improve end-organ function in order to make an ineligible patient eligible for HT, BTT and DT becomes somewhat arbitrary, as an increasing number of VADs as BTC will convert to DT due to the limited number of heart donors.

The evidence suggests VADs may facilitate myocardial recovery for individuals with reversible ventricular dysfunction, temporarily maintain circulation until transplant or extend the life expectancy of the terminally ill. VADs can improve survival, quality of life and functional status but are accompanied by a range of common complications, particularly with the newer continuous-flow (CF) LVADs. 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 LVADs 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 VADs may improve survival in many cases, associated adverse events and small improvements in QOL may limit their cost-effectiveness below conventionally held willingness-to-pay thresholds. Limited RCTs 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 MCS beyond criteria established for FDA-approval. In adult populations, some generalizations from consensus-based guidelines can be made:

- **As BTT,** the efficacy of surgically-implanted LVADs is demonstrated in numerous uncontrolled trials and trials comparing different VADs among patients awaiting HT who have no other options for survival. Evidence for earlier VAD implantation in less severely ill patients (e.g., those not yet on inotropic support) requires further study.
- **As BTT,** BiVADs and the TAH are available for patients with biventricular HF who meet criteria for HT and are at risk of imminent death. The effectiveness of temporary TAH has been established only in patients with idiopathic and ischemic cardiomyopathies in a hospital setting.
- **As DT,** LVADs improve outcomes in patients who are not candidates for HT and can be considered for patients who are expected to be on a long-term waiting list for HT. Patient selection is based on enrollment criteria in pivotal RCTs used to support FDA approval. Studies have not validated other preoperative variables to further refine patient selection and thereby improve patient outcomes. The safety and efficacy of BiVADs or TAH as DT or TAH used with a portable driver outside the hospital setting have not been established.
- **As a BTC,** this concept has not been standardized, and the decision to label a given VAD implantation as BTC (instead of BTT or DT) 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 LVADs as BTC is in-between that of BTT and DT, but results from RCTs are lacking.
- **As a BTR,** VADs approved for temporary use (extracorporeal or percutaneous VADs) in specific situations are available, but evidence of effectiveness is limited and conflicting. Guidelines vary in their enthusiasm for pVADs, but most recommend them as an option in the settings of PCI and CS/HF post-cardiotomy in patients for whom established treatments provide or are likely to provide inadequate hemodynamic support. Extracorporeal VADs provide temporary hemodynamic support for patients in acute HF or CS who otherwise faced an extremely high risk of mortality, but substantial uncertainty exists regarding the relative benefits versus alternatives (e.g., ECMO).

**Pediatrics:**

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

The most commonly used method of MCS in children is ECMO, and the only percutaneous device approved in the United States for short-term cardiac support in children is the IABP. ECMO 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%. As improvements in device design has allowed for lower pump volumes, there is interest in extending VADs to high-risk populations (e.g., small infants and those with complex congenital heart disease) for whom the options for MCS are more limited. VADs as BTR and DT are active areas of investigation in clinical trials and INTERMACS registry analyses. Femoral vessel size limits the use of current FDA-approved pVADs in small children.

**Summary of clinical evidence:**
### Health Quality Ontario (2016)  
**CF-LVADs as DT**

**Key points:**
- Overview of three systematic reviews and one observational study and three cost-effectiveness analyses (two from U.S. perspective) of adults with ESHF who are ineligible for HT (approximately 2,795 total patients, not clearly defined).
- Moderate quality evidence that CF-LVADs improve survival but more adverse events versus MM.
- Low quality evidence suggests CF-LVADs improve quality of life (QoL).
- The cost-effectiveness of LVAD as DT over MM was relatively high; Incremental cost-effectiveness ratios (ICERs) remained above traditional thresholds (e.g., $50,000 or $100,000 per quality-adjusted life year [QALY]).

### Neyt (2016) for the Belgium KCE  
**LVADs as DT or BTC**

**Key points:**
- Systematic review of four systematic reviews for adverse events, three RCTs (two published, one unpublished in progress) and five INTERMACS registry studies. Patients with NYHA class III/IV ESHF or CS.
- DT (2 RCTs, 329 total patients):
  - Versus medical management (MM), LVAD improved survival and QoL in patients with ESHF, particularly newer continuous-flow (CF) LVADs.
  - 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 HF requiring inotropic support; 2.9% and 6.5% device failure rates at 12 and 24-months post-implantation, respectively.
- No RCTs done on LVADs as a BTC. Observational data suggest overall, long-term survival is in-between that of BTT and DT patients. Subsets have similar survival to DT. Inconclusive evidence to compare outcomes of initial implant strategy versus other treatment strategies.
- LVADs as BTC not cost-effective, as increasing the number of LVADs as BTC will convert to DT since the number of heart donors is not increasing.

### Ponikowski (2016) for the European Society of Cardiology  
**Guideline for management of acute and chronic HF**

**Key points:**
- MCS indicated for patients with either chronic or acute HF who cannot be stabilized with medical therapy to unload the failing ventricle and maintain sufficient end-organ perfusion.
- Majority of VAD implants are done at INTERMACS levels 1–3, but earlier VAD 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 recent trial.
- BTD: Extracorporeal, short-term MCS considered in refractory CS depending on patient age, comorbidities and neurological function.
- BTC: Usually LVAD. For patients with active infection, severe renal, pulmonary or hepatic dysfunction or uncertain neurological status after cardiac arrest or due to CS.
- BTT: LVAD or BiVAD. Consider in patients who have end-stage HF/EF despite optimal medical and device therapy and who are eligible for HT in order to improve symptoms, reduce the risk of HF hospitalization and the risk of premature death.
- BTR: typically LVAD for chronic ESHF; pMCS not proven or efficacious for CS.
- DT: LVAD for HT ineligible or long-term waiting list for HT. For patients who have end-stage HFrEF despite optimal medical and device therapy and who are not eligible for HT to reduce the risk of premature death.

### Hayes (2015a)  
**pLVAD as BTR for CS**

**Key points:**
- Systematic review of one RCT, two retrospective registry analyses and three
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| Impella 2.5 (Abiomed Inc.) | observational single arm studies of fair to very poor quality (n=22 to 154 patients).  
• pLVAD versus IABP: Similar safety profile and equivalent survival benefit, but greater improvement in some hemodynamic parameters with pLVAD (one fair-quality RCT and one poor-quality retrospective registry analysis).  
• Substantial uncertainty regarding relative benefits versus alternatives (ECMO, surgically implantable LVADs and other pLVADs).  
• Higher quality evidence needed before routine use. RCTs are ongoing. |
| Hayes (2015b; updated 2016) | **Key points:**  
• Systematic review of seven studies reported in 12 publications (n=20 to 448 patients); one fair-quality prospective RCT (PROTECT II trial), one poor-quality retrospective comparative cohort study and five very-poor-quality single arm studies.  
• Overall quality: Low due to lack of comparators, short follow up, underpowered RCT.  
• Comparable effectiveness versus IABP in controlling the incidence of major adverse events (MAE) during high-risk PCI.  
• Higher quality evidence needed to assess relative benefits versus IABP, ECMO, surgically implantable LVADs and other pLVADs used prophylactically to prevent hemodynamic compromise during PCI. |
| Hayes (2015c) | **Key points:**  
• Systematic review of one poor-quality retrospective comparative cohort study and three very-poor-quality retrospective non-comparative cohort studies (34-47 total patients).  
• 30-day mortality range 33% to 72.3%.  
• RCTs and other prospective comparative studies needed to evaluate safety and efficacy versus other technologies for hemodynamic support, and to better define patient selection criteria. |
| Hayes (2010; updated 2015) | **Key points:**  
• Systematic review and catalog of available literature including multiple retrospective single-arm studies with > 50 patients, comparative studies and other observational studies with overlapping patient populations; two reports of different outcomes from the same multicenter prospective cohort study of the EXCOR VAD (n=204) and five secondary analyses.  
• Conflicting findings regarding rates of survival-to-recovery or transplantation, overall survival and adverse events.  
• Multiple complications/adverse effects included risks of prolonged mechanical ventilation, right ventricular failure, worsening renal function, neurological complications, arrhythmias and bleeding.  
• Age < 1 year, weight <10 kg, certain noncardiac morbidities, congenital heart disease, elevated pre-implant bilirubin levels and ECMO use were associated with worse outcomes.  
• BiVAD not clearly superior to LVADs alone. |
| Hayes (2015d) | **Key points:**  
• Systematic review of 13 between-group comparisons and five retrospective single-arm studies with overlapping patient populations as BTT; no studies included as DT; three studies evaluated portable drivers.  
• Overall quality: Low to very low.  
• TAH-t versus matched controls (no TAH):  
  o Survival to transplant: 79% versus 46% (P<0.001).  
  o Overall survival at 1-year: 70% versus 31% (P<0.001) and at least comparable to other MCS types as BTT.  
• The effectiveness of TAH-t established only in adults with idiopathic and ischemic cardiomyopathies in a hospital setting. |
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<td>Rihal (2015) for the Society for Cardiovascular Angiography and Interventions, The ACC Foundation, The Heart Failure Society of America, And The Society for Thoracic Surgery (SCAI/ACC/HFSA/STS) Guideline for pMCS for advanced HF and CS IABP TandemHeart Impella 2.5, 5.0, CP ECMO</td>
<td>• Safety and efficacy of TAH-t as DT or used with a portable driver outside the hospital setting not established.</td>
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<td>Key points:</td>
<td>• INTERMACS 1 and 2 patients may be considered for temporary MCS support as a BTR, surgical MCS or HT.</td>
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<td>• pMCS superior hemodynamic support to pharmacologic therapy, particularly for Impella and TandemHeart devices.</td>
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<td>• Consider MCS for:</td>
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<td>• CS, early placement if fail to stabilize or improve quickly after initial interventions.</td>
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<td>• Isolated acute RVF complicated by CS.</td>
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<td>• High-risk PCI, particularly if patient is inoperable or has severely decreased EF or elevated cardiac filling pressures.</td>
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<td>• Acute decompensated HF:</td>
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<td>• pMCS for continued deterioration after initial interventions.</td>
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<td>• MCS in candidates for surgically implanted VADs 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 MCSs 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 pMCS, veno-arterial ECMO or LVAD implantation with inotropic support.</td>
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<td>• MCS may be more cost-effective for emergent support than surgical ECMO or VAD, and for elective use versus IABP.</td>
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<td>Borisenko (2014)</td>
<td>Key points:</td>
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<td>RVAD as BTT, DT or BTR CentriMag</td>
<td>• Systematic review and meta-analysis of 53 publications (999 total adult and pediatric patients).</td>
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<td>• Overall quality: Low. Predominately retrospective case series.</td>
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<td>• Significant survival benefits to patients with cardiorespiratory failure due to:</td>
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<td>• Pre-cardiotomy CS 82% (95% confidence interval [CI] 70 to 92%).</td>
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<td>• Post-cardiac surgery CS 63% (95% CI 46 to 78%) in VAD.</td>
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<td>• Post-HT rejection or failure 62% (95% CI 46 to 76%).</td>
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<td>• Post-LVAD placement right ventricular failure 83% (95% CI 73 to 92%).</td>
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<td>• 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).</td>
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<td>• Adverse event rates are higher in pediatric populations than adults, but only bleeding and thrombosis rate differences were statistically significant between groups.</td>
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<td>• 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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<td>Hayes (2014)</td>
<td>Key points:</td>
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<td>TAH for BTT in children SynCardia TAH with the Freedom Portable Driver (SynCardia Systems Inc.)</td>
<td>• Search and summary of seven abstracts reporting TAH in pediatric patients: four case reports, three review articles (one with a case report), one case series.</td>
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<td>• Insufficient published evidence to assess the safety and/or impact on health outcomes or patient management in the pediatric population.</td>
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<td>Land (2014)</td>
<td>Key points:</td>
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<td>RVAD as BTT or BTR post</td>
<td>• Best evidence synthesis of 13 case series (three animal studies, 10 retrospective cohort)</td>
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<td>cardiotomy or HT Impella Recover RD CentriMag</td>
<td>Improved hemodynamic stability during and after RVAD support: central venous pressure ($P = 0.005$), mean pulmonary artery pressures ($P &lt; 0.01$), increases in RV cardiac output ($P &lt; 0.05$), RV ejection fraction ($P &lt; 0.05$), RV stroke work ($P &lt; 0.05$) and pulmonary artery oxygen saturations ($P &lt; 0.05$). Complications included bleeding, thromboembolism and sepsis. Higher mortality with percutaneous RVAD versus surgical RVAD (80% versus 44%).</td>
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<td>Feldman (2013) for the International Society for Heart and Lung Transplantation (ISHLT) Guidelines for MCS</td>
<td>Key points: Candidates should have NYHA functional class and INTERMACS profile determined. Management guided by individual clinicians and center-specific protocols. Few randomized studies to guide patient selection and care of the MCS 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.</td>
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<td>Sutcliffe (2013) LVADs as BTT or DT Generation II: HeartMate II (Thoratec Corp., CA, USA), Jarvik 2000 FlowMarker (Jarvik Heart, Inc., New York, NY, USA), MicroMed DeBakey Generation III: HeartWare HVAD, Berlin Heart INCOR, DuraHeart LVAS</td>
<td>Key points: Systematic review of 40 single-arm prospective or retrospective case series ($\geq 50$ patients) of adults (age $\geq 16$ years) with advanced HF eligible for HT; 29 series studied HeartMate II. No high-quality comparative empirical studies of VADs as BTT versus MM or as DT versus BTT. 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% HF; 11 to 32% reoperation; and 3 to 53% renal failure. Statistically significant improvements in QoL and functional status reported in studies of two devices (HeartMate II and HeartWare). Variety of measures used. Patients with advanced HF with existing vascular and renal function and whose QoL and life expectancy are poor may accept a high risk of adverse events to achieve a better QoL post-transplant.</td>
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<tr>
<td>Yancy (2013) for the ACCF/AHA Guideline on management of HF</td>
<td>Key points: MCS is beneficial in carefully selected patients with stage D (refractory) HF with reduced ejection fraction (HFrEF) as either BTT or BTR (Level of Evidence: B [data derived from single RCT or nonrandomized studies in select populations]). Nondurable MCS, including percutaneous and extracorporeal VADs, is reasonable as a BTR or “bridge to decision” for carefully selected patients with HFrEF with acute, profound hemodynamic compromise. (Level of Evidence: B). Durable MCS as DT is reasonable to prolong survival for carefully selected patients with stage D HFrEF. (Level of Evidence: B).</td>
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<tr>
<td>Peura (2012) for the AHA Guidelines for MCS</td>
<td>Key points: Uses for MCS: BTT for patients who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a HT. (Class I; Level of Evidence B). BTT for patients whose HT ineligibility is solely to pulmonary hypertension related to HF alone (Class IIa; Level of Evidence B). DT for patients: 1) with advanced HF, high 1-year mortality resulting from HF and absence of other life-limiting organ dysfunction; 2) who are ineligible for HT (Class I; Level of Evidence B; ) and 3) pre-advanced HF early referral (Class IIa; Level of Evidence B). Elective rather than urgent implantation of DT after optimal medical therapy for</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Cheng (2009) | advanced HF patients who are failing medical, surgical and/or device therapies (Class IIa; Level of Evidence C).  
- BTR for hemodynamically compromised patients with HF with reversible end-organ dysfunction and/or relative contraindications to HT/durable MCS (Class IIa; Level of Evidence C).  
- BTD or BTR in CS when impossible to fully determine candidacy for HT to determine neurological recovery and to stabilize potentially reversible comorbidities.  
- Extracorporeal devices as salvage support for patients in CS who otherwise faced an extremely high risk of mortality.  
- Percutaneous MCS for temporary support during high-risk PCI in the cardiac catheterization laboratory and for postcardiotomy HF and CS.  
- Recommend using the device that is familiar to the team and can best serve the needs of the patient. |
| Rosenthal (2004) for the ISHLT Guidelines for HF in children | Key points:  
- Systematic review of three RCTs (TandemHeart [two trials], Impella [one trial]; 100 total patients).  
- Results pLVAD versus IABP:  
  - 30-day mortality: 45% versus 43 (RR 1.06, 95% CI 0.68–1.66; P=0.80)  
  - pLVAD offers superior hemodynamic support: higher cardiac index (Weighted mean difference [MD] 0.35 L/min/m², 95% CI 0.09–0.61), higher mean arterial pressure (MD 12.8 mmHg, 95% CI 3.6–22.0), and lower pulmonary capillary wedge pressure (MD 25.3 mm Hg, 95% CI 29.4 to 21.2).  
  - PVAD had higher incidence of leg ischemia and device-related bleeding; similar complication rates within both types of pLVADs.  
- Results do not support pLVAD as replacement for IABP. |

### Glossary

**Ejection fraction (EF)** — A reflection of the heart’s pumping ability, measured as the percentage of blood pumped out of a filled ventricle with each contraction. A normal heart’s EF is between 50 and 70 percent.

**Cardiogenic shock (CS)** — A life-threatening complication typically of acute myocardial infarction (MI) resulting in ventricular pump failure and reduced end-organ perfusion.

**Heart failure (HF)** — A chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. Two types of HF are:
**HF with preserved EF (HFpEF)** — HF characterized by clinical evidence of cardiac dysfunction but normal left ventricular volumes and normal or near normal left ventricular ejection fraction (LVEF >40 percent); formerly referred to as “diastolic” HF.

**HF with reduced EF (HFrEF)** — HF characterized by the left ventricle’s inability to contract normally (LVEF ≤40 percent); formerly referred to as “systolic” HF.

**Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)** — The United States national registry for patients who are receiving FDA-approved durable mechanical circulatory support devices to treat advanced HF. Goals of data collection include refinement of patient selection criteria and guidance for clinical application and technological improvements.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**

American Heart Association (AHA). About Heart Failure. Last reviewed April 6, 2015. AHA website. [http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/About-Heart-Failure_UCM_002044_Article.jsp#.V2swy_72bIU](http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/About-Heart-Failure_UCM_002044_Article.jsp#.V2swy_72bIU). Accessed June 22, 2016.


**Clinical trials:**

Searched clinicaltrials.gov on June 28, 2016 using terms "ventricular assist device" | Open Studies | United States. 37 studies found, 18 relevant. Selected trials include:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**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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<td>Heart transplant, with or without recipient cardiectomy</td>
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<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 transeptal puncture</td>
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**Appendix**

NYHA Functional Classification of HF (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.

ACCF/AHA Stages of HF (Hunt, 2009):

- **Stage 1.** At high risk for HF but without structural heart disease or symptoms of HF.
- **Stage 2.** Structural heart disease but without signs or symptoms of HF.
- **Stage 3.** Structural heart disease with prior or current symptoms of HF.
- **Stage 4.** Refractory HF requiring specialized interventions IV Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.

INTERMACS stages for classifying patients with advanced HF at time of implant (2016):

- **Stage 1.** Critical CS, “crash and burn.”
- **Stage 2.** Progressive decline, on inotropic support or in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia or other intolerance.
- **Stage 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).
- **Stage 4.** Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL.
- **Stage 5.** Exertion intolerant living predominantly within the house or housebound.
- **Stage 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.
- **Stage 7.** Advanced NYHA Class III, clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent.