**Total Artificial Hearts and Implantable Ventricular Assist Devices**

**Introduction**

An implantable ventricular assist device (VAD) is a battery operated mechanical pump that can help your heart pump blood out to the rest of your body. The VAD is surgically put in your body. It has a tube that pulls blood from the left ventricle (the main pumping chamber of the heart) and pumps the blood into the aorta (the main artery leaving the heart). The blood is then sent out to the rest of the body. Another device, called a total artificial heart (TAH), can be implanted in the chest to replace both of the lower pumping chambers in the heart. This policy identifies the criteria needed for a VAD or TAH to be covered as medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bridge to Transplantation</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Implantable ventricular assist devices (VADs) | FDA approved ventricular assist devices (VADs) may be considered medically necessary as a bridge to heart transplantation for adult and pediatric patients:  
• Who are currently listed as heart transplantation candidates and are not expected to survive until a donor heart can be obtained  
OR  
• Who are undergoing evaluation to determine candidacy for heart transplantation |
| Total artificial hearts (TAHs) with FDA-approval | FDA-approved total artificial hearts (TAHs) implantation may be considered medically necessary as a bridge to heart transplantation for patients with ALL of the following:  
• Biventricular failure who have no other reasonable medical or surgical treatment options  
AND  
• They are ineligible for other univentricular or biventricular support devices  
AND  
• They are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation  
AND  
• They are not expected to survive until a donor heart can be obtained |
| **Destination Therapy** | |
| Implantable VADs with FDA approval or clearance | FDA approved implantable VADs may be considered medically necessary as destination therapy for patients who meet ALL of the following:  
• They have end-stage heart failure  
AND  
• They are ineligible for human heart transplant (see below)  
AND  
• They meet the following REMATCH Study criteria:  
  o New York Heart Association class IV heart failure for ≥60 days,


<table>
<thead>
<tr>
<th>Device</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>o New York Heart Association class III or IV for 28 days</td>
<td></td>
</tr>
<tr>
<td>AND</td>
<td></td>
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<tr>
<td>o They received ≥14 days of support with intra-aortic balloon pump</td>
<td></td>
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<tr>
<td>OR</td>
<td></td>
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<tr>
<td>o They are dependent on intravenous inotropic agents, with 2 failed weaning attempts</td>
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</tbody>
</table>

Additionally, patients must not be candidates for human heart transplant for ANY of the following reasons:
- Age >65 years
- OR
- Insulin-dependent diabetes with end-organ damage
- OR
- Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days)
- OR
- Presence of other clinically significant condition

### Postcardiotomy Setting/Bridge to Recovery

| Implantable VADs with FDA approval | FDA approved implantable VADs may be considered medically necessary in patients who are postcardiotomy (following open-heart surgery) and are unable to be weaned off cardiopulmonary bypass. |

### Investigational

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other applications of VADs or TAHs</td>
<td>Other applications of implantable VADs or TAHs are considered investigational, including, but not limited to, the use of TAHs as destination therapy. The use of non-FDA-approved implantable VADs or TAHs is considered investigational. Percutaneous VADs are considered investigational for all indications. (eg, TandemHeart®, Impella® 2.5, Impella 5.0 System)</td>
</tr>
</tbody>
</table>
### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met.

**For implantable ventricular assist devices (VADs) as bridge therapy for adult and pediatric patients, the record should include clinical documentation that:**

- Patient is currently listed as a heart transplant candidate but a heart is not yet available and patient’s own heart may not be able to keep patient alive until one is found
  
  **OR**

- It’s used during the evaluation to see if patient is a candidate for a heart transplant

**For total artificial hearts (TAHs) with FDA-approval–bridge therapy, the record should include clinical documentation of ALL of the following:**

- Patient’s heart failure affects both sides of the heart and there are no other reasonable medical or surgical treatment options

  **AND**

- Patient is ineligible for any other support devices

  **AND**

- Patient is waiting for a donor heart or being evaluated for a donor heart

  **AND**

- Patient is not expected to survive until a donor heart can be obtained

**For implantable VADs with FDA approval or clearance – destination therapy, the record should include clinical documentation of ALL of the following:**

- Patient has end-stage heart failure

- Patient is not a candidate for human heart transplant due to the following reasons:
  - Age >65 years
  - Insulin-dependent diabetes with end-organ damage
  - Chronic renal failure (serum creatinine >2.5 mg/dL for ≥90 days)
  - Presence of other clinically significant condition

- Patient meets the following REMATCH study criteria:
  - New York Heart Association class IV heart failure for ≥60 days
  -
**Documentation Requirements**

- New York Heart Association class III or IV for 28 days
  
  **AND**

- They received ≥14 days of support with intra-aortic balloon pump

**OR**

- They are dependent on intravenous inotropic agents, with 2 failed weaning attempts

For implantable VADs with FDA approval – postcardiotomy, the record should include clinical documentation that:

- Patient had an open-heart surgery and is unable to be weaned off cardiopulmonary bypass

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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33927</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy</td>
</tr>
<tr>
<td>33928</td>
<td>Removal and replacement of total replacement heart system (artificial heart)</td>
</tr>
<tr>
<td>33929</td>
<td>Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
</tr>
<tr>
<td>33979</td>
<td>Insertion of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33981</td>
<td>Replacement of extracorporeal ventricular assist device device, single or biventricular, pump(s), single or each pump</td>
</tr>
<tr>
<td>33982</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33983</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass</td>
</tr>
<tr>
<td>33990</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only</td>
</tr>
<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>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>33992</td>
<td>Removal of percutaneous ventricular assist device at separate and distinct session from insertion</td>
</tr>
<tr>
<td>33993</td>
<td>Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion</td>
</tr>
</tbody>
</table>

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

### Related Information

Only 2 ventricular assist devices (VADs) have approval from the U.S. Food and Drug Administration for the pediatric population. The DeBakey VAD Child device and the Berlin Heart EXCOR Pediatric VAD have Food and Drug Administration approval through the humanitarian device exemption process. The DeBakey VAD is indicated for use in children ages 5 to 16 years who are awaiting a heart transplant (ie, a bridge to transplant) while the Berlin Heart EXCOR VAD is indicated for children with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support. See [Regulatory Status](#) and [Ongoing and Unpublished Clinical Trials](#) sections below.

Patients with VADs are classified by the United Network for Organ Sharing as status I (ie, persons who are most ill and are considered the highest priority for transplant).

The median duration for time on the device is between 20 days and 120 days.

In addition, patients must have sufficient space in the thorax and/or abdominal cavity for the device. In the case of the CardioWest Temporary Total Artificial Heart, this excludes patients with body surface areas less than 1.7 m² or who have a distance between the sternum and 10th anterior rib of less than 10 cm, as measured by computed tomography scan.

### Evidence Review
Description

A ventricular assist device (VAD) is a mechanical support attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy in those not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Background

Heart Failure

Heart failure may be the consequence of a number of etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body’s needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1, 3, and 5 years of 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Treatment

Ventricular Assist Devices

Implantable ventricular assist devices (VADs) are attached to the native heart, which may have enough residual capacity to withstand a device failure in the short term. In reversible heart failure conditions, the native heart may regain some function, and weaning and explanting of the mechanical support system after months of use has been described. VADs can be classified as internal or external, electrically or pneumatically powered, and pulsatile or continuous-flow. Initial devices were pulsatile, mimicking the action of a beating heart. More recent devices may use a pump, which provides continuous-flow. Continuous devices may move blood in a rotary or axial flow.

At least 1 VAD system developed is miniaturized and generates an artificial pulse, the HeartMate 3 Left Ventricular Assist System.²
Surgically implanted VADs represent a method of providing mechanical circulatory support for patients not expected to survive until a donor heart becomes available for transplant or for whom transplantation is contraindicated or unavailable. VADs are most commonly used to support the left ventricle, but right ventricular and biventricular devices may be used. The device is larger than most native hearts, and therefore the size of the patient is an important consideration. The pump may be implanted in the thorax or abdomen, or remain external to the body. Inflow to the device is attached to the apex of the failed ventricle, while outflow is attached to the corresponding great artery (aorta for left ventricle, pulmonary artery for the right ventricle). A small portion of the ventricular wall is removed for insertion of the outflow tube; extensive cardiotomy affecting the ventricular wall may preclude VAD use.

**Total Artificial Hearts**

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

A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in 2 patients but is currently experimental.3

**Percutaneous VADs**

Devices in which most of the system’s components are external to the body are for short-term use (6 hours to 14 days) only, due to the increased risk of infection and need for careful, in-hospital monitoring. Some circulatory assist devices are placed percutaneously (ie, are not implanted). They may be referred to as percutaneous VADs (pVADs). A pVAD is placed through the femoral artery. Two different pVADs have been developed, the TandemHeart and the Impella device. In the TandemHeart system, a catheter is introduced through the femoral vein and passed into the left atrium via transseptal puncture. Oxygenated blood is then pumped from the left atrium into the arterial system via the femoral artery. Adverse events associated with pVAD include access-site
complications such as bleeding, aneurysms, or leg ischemia. Cardiovascular complications can also occur, such as perforation, myocardial infarction, stroke, and arrhythmias.

**Summary of Evidence**

*Ventricular Assist Device*

For individuals who have end-stage heart failure who receive a VAD as a bridge to transplant, the evidence includes single-arm trials and observational studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. There is a substantial body of evidence from clinical trials and observational studies supporting implantable VADs as a bridge to transplant in patients with end-stage heart failure, possibly reducing mortality as well as improving quality of life. These studies have reported that substantial numbers of patients have survived to transplant in situations in which survival would not be otherwise expected. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a VAD as destination therapy, the evidence includes a trial and multiple single-arm studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. A well-designed trial, with 2 years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for heart transplant. Despite an increase in adverse events, both mortality and quality of life appear to be improved for these patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

*Total Artificial Heart*

For individuals who have end-stage heart failure who receive a TAH as a bridge to transplant, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Percutaneous Ventricular Assist Device**

For individuals with cardiogenic shock or who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes randomized controlled trials. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Four randomized controlled trials of pVAD vs IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates associated with pVAD use. Another randomized controlled trial comparing pVAD with IABP as an adjunct to high-risk percutaneous coronary interventions was terminated early due to futility; analysis of enrolled subjects did not demonstrate significant improvements in the pVAD group. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cardiogenic shock refractory to IABP who receive a pVAD, the evidence includes case series. Relevant outcomes are overall survival, symptoms, morbid events, functional outcomes, quality of life, and treatment-related mortality and morbidity. Case series of patients with cardiogenic shock refractory to IABP have reported improved hemodynamic parameters following pVAD placement. However, these uncontrolled series do not provide evidence that pVADs improve mortality, and high rates of complications have been reported with pVAD use. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01774656a</td>
<td>Remission From Stage D Heart Failure (RESTAGE-HF)</td>
<td>40</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT01627821a</td>
<td>Evaluation of the Jarvik 2000 Left Ventricular Assist System With Post-Auricular Connector—Destination Therapy Study</td>
<td>350</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT01369407</td>
<td>REVIVE-IT Registry (REVIVAL: Registry Evaluation of Vital Information For VADs in Ambulatory Life)</td>
<td>400</td>
<td>Jun 2019</td>
</tr>
<tr>
<td>NCT01966458a</td>
<td>A Prospective, Randomized, Controlled, Unblinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist Device System for Destination Therapy of Advanced Heart Failure</td>
<td>494</td>
<td>Aug 2020</td>
</tr>
<tr>
<td>NCT02232659</td>
<td>SynCardia 70cc Temporary Total Artificial Heart (TAH-t) for Destination Therapy (DT)</td>
<td>38</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT02326402</td>
<td>THEME Registry: TandemHeart Experiences and Methods</td>
<td>200</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT01187368a</td>
<td>A Prospective Study to Evaluate the Safety and Efficacy of the EVAHEART LVAS for Use as a Bridge-to-Transplant</td>
<td>20</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT02387112</td>
<td>Early Versus Emergency Left Ventricular Assist Device Implantation in Patients Awaiting Cardiac Transplantation</td>
<td>500</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT02459054</td>
<td>SynCardia 50cc Temporary Total Artificial Heart (TAH-t) as a Bridge to Transplant</td>
<td>72</td>
<td>Jun 2024</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02468778</td>
<td>Supporting Patients Undergoing High-Risk PCI Using a High-Flow PERcutaneous Left Ventricular Support Device (SHIELD II)</td>
<td>425</td>
<td>Jan 2018 (suspended)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate
reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2014. Vetting focused on the use of percutaneous ventricular assist devices (pVADs) under the American Heart Association and American College of Cardiology guidelines (2013) and on the use of total artificial heart as destination therapy. All providing input supported the use of implantable ventricular assist devices as destination therapy subject to the guidelines in the policy statements. Most providing input considered total artificial hearts to be investigational for destination therapy; reviewers noted that there are limited clinical trial data to support the use of total artificial hearts as destination therapy.

Most providing input considered pVADs to be investigational as a “bridge to recovery” or “bridge to decision” and for all other indications. Some reviewers noted that pVADs may improve patients’ hemodynamics better than other alternatives, such as an intra-aortic balloon pump, but are associated with more complications. Some noted that, despite a lack of evidence to indicate that pVADs improve overall outcomes, there may be cases when pVADs may be considered to support an intervention or treatment for a life-threatening condition.

**Practice Guidelines and Position Statements**

*Society for Cardiovascular Angiography and Interventions et al*

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

The American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of America (2017) published a focused update of the 2013 recommendations released by the American College of Cardiology Foundation and AHA. Left ventricular assist device was one of several treatment options recommended for patients with refractory New York Heart Association class III or IV heart failure (stage D). If symptoms were not improved after guidelines-directed management and therapy, which included pharmacologic therapy, surgical management and/or other devices, then left ventricular assist device would be an additional treatment option.

The 2017 update focused on changes in sections regarding biomarkers, comorbidities, and prevention of heart failure, while many of the previous recommendations remained unchanged. The American College of Cardiology Foundation and AHA (2013) released guidelines for the management of heart failure that included recommendations related to the use of MCS, including both durable and nondurable MCS devices. The guidelines categorized percutaneous ventricular assist devices (pVADs) and extracorporeal VADs as nondurable MCS devices. Table 2 provides class IIA guidelines on MCS devices.

Table 2. 2013 Guidelines on MCS

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COE</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;MCS is beneficial in carefully selected patients with stage D HFrEF in whom definitive management (eg, cardiac transplantation) or cardiac recovery is anticipated or planned.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>&quot;Nondurable MCS, including the use of percutaneous and extracorporeal ventricular assist devices (VADs), is reasonable as a “bridge to recovery” or “bridge to decision” for carefully selected patients with HFrEF with acute, profound hemodynamic compromise.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>&quot;Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
</tbody>
</table>

COE: class of evidence; HFrEF: heart failure with reduced ejection fraction; LOE: level of evidence; MCS: mechanical circulatory support.

These 2013 guidelines also noted:

Although optimal patient selection for MCS remains an active area of investigation, general indications for referral for MCS therapy include patients with LVEF [left ventricular ejection fraction] <25% and NYHA [New York Heart Association] class III-IV functional status despite GDMT [guideline-directed medical therapy], including, when indicated, CRT [cardiac
resynchronization therapy], with either high predicted 1- to 2-year mortality (eg, as suggested by markedly reduced peak oxygen consumption and clinical prognostic scores) or dependence on continuous parenteral inotropic support. Patient selection requires a multidisciplinary team of experienced advanced HF [heart failure] and transplantation cardiologists, cardiothoracic surgeons, nurses, and ideally, social workers and palliative care clinicians.

**American Heart Association**

AHA (2012) published recommendations for the use of MCS. These guidelines defined nondurable MCS as intraballoons pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 3 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

**Table 3. 2012 Guidelines on MCS**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COE</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“MCS for BTT indication should be considered for transplant-eligible patients with end-stage HF who are failing optimal medical, surgical, and/or device therapies and at high risk of dying before receiving a heart transplantation.”</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>“Implantation of MCS in patients before the development of advanced HF ... is associated with better outcomes. Therefore, early referral of HF patients is reasonable.”</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>“MCS with a durable, implantable device for permanent therapy or DT is beneficial for patients with advanced HF, high 1-year mortality resulting from HF, and the absence of other life-limiting organ dysfunction; who are failing medical, surgical, and/or device therapies; and who are ineligible for heart transplantation.”</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>“Elective rather than urgent implantation of DT can be beneficial when performed after optimization of medical therapy in advanced HF patients who are failing medical, surgical, and/or device therapies.”</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>&quot;Urgent nondurable MCS is reasonable in hemodynamically compromised HF patients with end-organ dysfunction and/or relative contraindications to heart transplantation/durable MCS that are expected to improve with time and restoration of an improved hemodynamic profile.”</td>
<td>IIAI</td>
<td>C</td>
</tr>
<tr>
<td>“These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF.”</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>“Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term”</td>
<td>IIA</td>
<td>B</td>
</tr>
</tbody>
</table>
The Heart Failure Society of America (HFSA)

The Heart Failure Society of America published guidelines in 2010 on surgical approaches to the treatment of heart failure. Table 4 lists recommendations on left VADs:

### Table 4. Guidelines on Left Ventricular Assist Devices

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients awaiting heart transplantation who have become refractory to all means of medical circulatory support should be considered for a mechanical support device as a bridge to transplant.”</td>
<td>B</td>
</tr>
<tr>
<td>“Permanent mechanical assistance using an implantable assist device may be considered in highly selected patients with severe HF refractory to conventional therapy who are not candidates for heart transplantation, particularly those who cannot be weaned from intravenous inotropic support at an experienced HF center.”</td>
<td>B</td>
</tr>
<tr>
<td>“Patients with refractory HF and hemodynamic instability, and/or compromised end-organ function, with relative contraindications to cardiac transplantation or permanent mechanical circulatory assistance expected to improve with time or restoration of an improved hemodynamic profile should be considered for urgent mechanical circulatory support as a ‘bridge to decision.’ These patients should be referred to a center with expertise in the management of patients with advanced HF.”</td>
<td>C</td>
</tr>
</tbody>
</table>

HF: heart failure; SOE: strength of evidence.

Medicare National Coverage

Medicare has a national coverage determination (NCD) for artificial hearts and related devices, including VADS. The NCD mandates coverage for VADs in the postcardiotomy setting as long as the following conditions are met:

- The VAD has “approval from the FDA” for post-cardiotomy support.
- The VAD is “used according to the FDA-approved labeling instructions.”

The NCD also mandates coverage for VADs as a bridge-to-transplant as long as the following conditions are met:
• The VAD has approval from the FDA for the bridge-to-transplant indication.

• The VAD is “used according to the FDA-approved labeling instructions.”

• “The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center... “

• “The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.”

The NCD mandates coverage for VADs as destination therapy as long as the following conditions are met:

• The VAD has approval from FDA for the destination therapy indication.

• Patient selection:
  o New York Heart Association Class IV end-stage left ventricular failure
  o Not candidates for heart transplantation
  o Failed to respond to optimal medical management,
  o Left ventricular ejection fraction (LVEF) <25%, and,
  o Demonstrated functional limitation

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

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

The NCD mandates coverage for artificial hearts as a bridge to transplant or destination therapy when performed under coverage with evidence development when a clinical study meets the criteria outlined in the Medicare policy.
Regulatory Status

A number of mechanical circulatory support devices have been approved or cleared for marketing by the U.S. Food and Drug Administration (FDA). These devices are summarized in Table 5 and Table 6.

Table 5. Available Mechanical Circulatory Support Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Approval Date</th>
<th>FDA Clearance</th>
<th>PMA, HDE, or 510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(VADs)</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoratec® IVAD</td>
<td>Thoratec</td>
<td>Aug 2004</td>
<td>PMA supplement</td>
<td>P870072</td>
<td>Bridge to transplant and postcardiotomy</td>
</tr>
<tr>
<td>DeBakey VAD® Child</td>
<td>MicroMed</td>
<td>Feb 2004</td>
<td>HDE</td>
<td>H030003</td>
<td>Bridge to transplant in children 5-16 y of age</td>
</tr>
<tr>
<td>HeartMate II®</td>
<td>Thoratec</td>
<td>Apr 2008</td>
<td>PMA</td>
<td>P060040</td>
<td>Bridge to transplant and destination</td>
</tr>
<tr>
<td>CentriMag®</td>
<td>Levitronix (now Thoratec)</td>
<td>Oct 2008</td>
<td>HDE</td>
<td>H070004</td>
<td>Postcardiotomy</td>
</tr>
<tr>
<td>Berlin Heart EXCOR® Pediatric VAD</td>
<td>Berlin</td>
<td>Dec 2011</td>
<td>HDE</td>
<td>H100004</td>
<td>Bridge to transplant</td>
</tr>
<tr>
<td>HeartWare® Ventricular Assist System</td>
<td>HeartWare</td>
<td>Dec 2012</td>
<td>PMA</td>
<td>P100047</td>
<td>Bridge to transplant</td>
</tr>
<tr>
<td>HeartMate 3™ Left Venticular Assist System</td>
<td>Thoratec</td>
<td>Aug 2017</td>
<td>PMA</td>
<td>P160054</td>
<td>Bridge to transplant and destination</td>
</tr>
</tbody>
</table>

FDA: U.S. Food and Drug Administration; HDE: humanitarian device exemption; PMA: premarket approval
**Ventricular Assist Devices**

In 1995, the Thoratec® Ventricular Assist Device System (Thoratec Corp.,) was approved by FDA through the premarket approval process as a bridge to transplantation in patients suffering from end-stage heart failure. The patient should meet all of the following criteria:

- Candidate for cardiac transplantation,
- Imminent risk of dying before donor heart procurement, and
- Dependence on, or incomplete response to, continuous vasopressor support.

In 1998, supplemental approval for this device was given for the indication for postcardiotomy patients unable to be weaned from cardiopulmonary bypass. In June 2001, supplemental approval was given for a portable external driver to permit excursions within a 2-hour travel radius of the hospital when accompanied by a trained caregiver. In 2003, supplemental approval was given to market the device as Thoratec® Paracorporeal VAD. In 2004, supplemental approval was given to a modified device to be marketed as the Thoratec® Implantable VAD for the same indications. In 2008, supplemental approval was given to rescind Paracorporeal VAD use.

In August 2016, HeartWare® recalled its VAD Pumps due to a design flaw that was deemed by FDA as potentially causing serious injuries or death (class I recall). The devices affected were manufactured and distributed from March 2006 and May 2018. FDA product codes 204 and 017.

A class I recall was issued for the HeartMate 3™ in April 2018 affecting all manufacturing dates. FDA product code: DSQ.

**Total Artificial Heart**

In 2004, the temporary CardioWest™ Total Artificial Heart (SynCardia Systems) was approved by the FDA through the premarket approval process for use as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. This device is also intended for use inside the hospital. In 2010, FDA approved a name change to SynCardia Temporary Total Artificial Heart. FDA product code: LOZ.

In 2006, the AbioCor® Implantable Replacement Heart System (Abiomed) was approved by the FDA through the humanitarian device exemption (H040006) process for use in severe biventricular end-stage heart disease patients who are not cardiac transplant candidates and who:
- Are younger than 75 years of age;
- Require multiple inotropic support;
- Are not treatable by left VAD destination therapy; and
- Are not weanable from biventricular support if on such support.

In addition to meeting other criteria, patients who are candidates for the AbioCor® TAH must undergo a screening process to determine if their chest volume is large enough to hold the device. The device is too large for approximately 90% of women and for many men.

**Percutaneous VADs (Circulatory Assist Devices)**

**Table 6. Available Mechanical Circulatory Support Devices**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Approval Date</th>
<th>FDA Clearance</th>
<th>PMA, 510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>TandemHeart®</td>
<td>Cardiac Assist</td>
<td>Sep 2005</td>
<td>510(k)</td>
<td>K110493</td>
<td>Temporary left ventricular bypass of ≤6 h</td>
</tr>
<tr>
<td>Impella® Recover LP 2.5</td>
<td>Abiomed</td>
<td>May 2008</td>
<td>510(k)</td>
<td>K063723</td>
<td>Partial circulatory support using extracorporeal bypass control unit for ≤6 h</td>
</tr>
<tr>
<td>Impella 2.5 System</td>
<td>Abiomed</td>
<td>Mar 2015</td>
<td>PMA</td>
<td>P140003</td>
<td>Temporary ventricular support for ≤6 h</td>
</tr>
</tbody>
</table>

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

**Comparative Efficacy of Left VAD Devices**

The mechanism of operation of left VADs has changed since their introduction. The earliest devices were pulsatile positive displacement pumps. These pumps have been largely replaced by axial continuous-flow pumps. More recently centrifugal continuous-flow pumps have also been introduced.
The evidence of the comparative efficacy of centrifugal continuous-flow vs axial continuous-flow devices consists of 2 randomized controlled trials of 2 different centrifugal continuous-flow devices. The MOMENTUM 3 trial compared HeartMate 3 centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as a bridge to transplant or destination therapy. HeartMate 3 received PMA approval in August 2017 but was recalled in April 2018. The ENDURANCE trial compared HeartWare centrifugal continuous-flow device with the HeartMate II axial continuous-flow device in patients indicated for circulatory support as destination therapy. HeartWare is FDA-approved as a bridge to transplantation device. Both trials found the centrifugal device to be noninferior to the axial device for the primary, composite outcome including measures of survival, freedom from disabling stroke, and freedom from device failure. While there are fewer device failures with the centrifugal devices without a significant increase in disabling stroke, the HeartWare device was associated with increased risk of any stroke over a period of 2 years.

The evidence on the comparative efficacy of continuous-flow vs pulsatile-flow devices consists of a randomized controlled trial and several nonrandomized comparative studies. The randomized controlled trial reported fairly large differences in a composite outcome measure favoring the continuous-flow devices, with increases in revision and reoperation rates for the pulsatile device group being the largest factor driving the difference in outcomes. Other nonrandomized comparative studies, including a database study with large numbers of patients, have not reported important differences in clinical outcomes between devices.

References

26. Dickstein K, Cohen-Solal A, Filippatos G, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of


43. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/14/98</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>06/01/99</td>
<td>Replace policy - Policy updated to include new FDA-approved devices.</td>
</tr>
<tr>
<td>06/27/00</td>
<td>Replace policy - Scheduled review; no criteria changes.</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace policy - Policy reviewed: Rationale section expanded, references added. Policy statement on use of VADs in patients who are not transplant candidates deleted; this topic will be addressed in a separate policy. Policy statement otherwise unchanged.</td>
</tr>
<tr>
<td>04/15/03</td>
<td>Replace policy - Policy statement revised to include 2002 TEC Assessment conclusions regarding VADs in patients who are not transplant candidates, ie, &quot;destination&quot; therapy. Title changed from Ventricular Assist Devices as a Bridge to Heart Transplantation.</td>
</tr>
<tr>
<td>10/16/03</td>
<td>Replace policy - Policy statement revised to limit medically necessary indications to FDA approved devices.</td>
</tr>
<tr>
<td>02/10/04</td>
<td>Replace policy - Policy statement added regarding investigational status of total artificial hearts. Additional 2003 Category III CPT codes added.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace policy - Policy statement revised to indicate that a total artificial heart may be considered medically necessary as a bridge to transplant, based on FDA approval for that indication.</td>
</tr>
<tr>
<td>04/21/06</td>
<td>Codes Updated - No other changes</td>
</tr>
<tr>
<td>05/26/06</td>
<td>Scope and Disclaimer Updates - No other changes.</td>
</tr>
<tr>
<td>07/11/06</td>
<td>Replace policy - Policy updated with literature review; references added; policy statement unchanged.</td>
</tr>
<tr>
<td>11/14/06</td>
<td>Replace policy - Policy updated with FDA approval of total artificial heart. Policy</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12/11/06</td>
<td>Codes Updated - No other changes</td>
</tr>
<tr>
<td>10/14/08</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. Codes 37.52-37.66 added, references added.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Codes Update - New 2010 codes added.</td>
</tr>
</tbody>
</table>
| 11/09/10   | Replace policy - Policy updated with literature search; references 1, 10, 19, 29 and 30 added. Extensive editing completed. Policy statements revised to address only implantable VADs and total artificial hearts.                                                                 |}

**Statement unchanged; total artificial hearts are investigational. References added.**
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>through July 22, 2017; references 5-7, 34, 47, 49-51, 70, 72, 83, 85, 88, and 93 added. Policy statements revised to add information regarding total artificial hearts and implantable ventricular assist devices. Codes updated; removed 33999 and added 0051T, 0052T, and 0053T.</td>
</tr>
<tr>
<td>03/03/18</td>
<td>Coding update; added note that CPT codes 0051T, 0052T, and 0053T were terminated 1/1/18. Added new CPT codes 33927, 33928, and 33929 (new codes effective 1/1/18).</td>
</tr>
<tr>
<td>11/01/18</td>
<td>Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; several references added. Other than minor editing for clarity, policy statements unchanged. Added CPT codes 33975, 33976, 33979, 33981, 33982, 33983.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Coding update, removed CPT codes 0051T, 0052T, and 0053T as they were terminated 1/1/18.</td>
</tr>
</tbody>
</table>

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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)


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Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

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