Total Artificial Hearts and Implantable Ventricular Assist Devices

Description

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

Ventricular Assist Devices

Implantable 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 one 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 the left ventricle, a 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 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 two patients but is currently experimental.

**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 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. The Impella device is introduced through a femoral artery catheter. In this device, a small pump is contained within the catheter placed into the left ventricle. Blood is pumped from the left ventricle, through the device, and into the ascending aorta. 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.

**OBJECTIVE**

The objective of this evidence review is to determine whether ventricular assist devices and total artificial hearts improve the net health outcome in individuals with end-stage heart failure or cardiogenic shock.

**POLICY STATEMENT**

**Bridge to Transplantation**

Implantable ventricular assist devices (VADs) with Food and Drug Administration (FDA) approval or clearance may be considered medically necessary as a bridge to heart transplantation for patients who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Implantable VADs with FDA approval or clearance, including humanitarian device exemptions, may be considered medically necessary as a bridge to heart transplantation in children 16 years old or younger who are currently listed as heart transplantation candidates and not expected to survive until a donor heart can be obtained, or are undergoing evaluation to determine candidacy for heart transplantation.

Total artificial hearts (TAHs) with FDA-approved devices may be considered medically necessary as a bridge to heart transplantation for patients with biventricular failure who have no other reasonable medical or surgical treatment options, who are ineligible for other

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univentricular or biventricular support devices, and are currently listed as heart transplantation candidates or are undergoing evaluation to determine candidacy for heart transplantation, and not expected to survive until a donor heart can be obtained.

**Destination Therapy**

Implantable VADs with FDA approval or clearance may be considered *medically necessary* as destination therapy with end-stage heart failure patients who are ineligible for human heart transplant and who meet the following REMATCH Study criteria:

- New York Heart Association class IV heart failure for ≥60 days, or patients in New York Heart Association class III or IV for 28 days, received ≥14 days of support with intra-aortic balloon pump or dependent on intravenous inotropic agents, with 2 failed weaning attempts.

In addition, patients must not be candidates for human heart transplant for one or more 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 or clearance may be considered *medically necessary* in the postcardiotomy setting in patients who are unable to be weaned off cardiopulmonary bypass.

**Other Indications**

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 or cleared implantable VADs or TAHs is considered *investigational*.

Percutaneous VADs are considered *not medically necessary* for all indications.

**POLICY GUIDELINES**

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.

In general, candidates for bridge to transplant implantable VADs are those who are considered appropriate heart transplant candidates but who are unlikely to survive the waiting period until a human heart donor is available. Some studies have included the following hemodynamic selection criteria: either a left atrial pressure of 20 mm Hg or a cardiac index of less than 2.0 L/min/m while receiving maximal medical support. 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.

Contraindications for bridge to transplant VADs and total artificial hearts include conditions that would generally exclude patients for heart transplant. Such conditions are chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders, and inadequate psychosocial support. Due to potential problems with adequate function of the VAD or total artificial heart, implantation is also contraindicated in patients with uncorrected valvular disease. See evidence review 7.03.09 (heart transplantation) for further discussion of heart transplant candidacy.

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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 m\(^2\) or who have a distance between the sternum and 10th anterior rib of less than 10 cm, as measured by computed tomography scan.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA 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 Tables 1 and 2 and discussed in the following sections.

**Table 1. 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>Thoratec IVAD</td>
<td>Thoratec</td>
<td>Aug 2004</td>
<td>PMA Supp</td>
<td>P870072</td>
<td>Bridge to transplant and postcardiomy</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</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>Postcardiomy</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></td>
<td></td>
<td>June 2017</td>
<td>PMA</td>
<td>P160035</td>
<td></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 Ventricular Assist System</td>
<td>Thoratec</td>
<td>Aug 2017</td>
<td>PMA</td>
<td>P160054</td>
<td>Bridge to transplant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oct 2018</td>
<td>PMA</td>
<td>P160054/S008</td>
<td>Destination</td>
</tr>
</tbody>
</table>

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

**Ventricular Assist Devices**

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In 1995, the Thoratec Ventricular Assist Device System (Thoratec Corp.) was approved by the FDA through the premarket approval process as a bridge to transplantation in patients with 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 of 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 the 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, the 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 FDA through the humanitarian device exemption (H040006) process 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 2. 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>
</tbody>
</table>

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Impella 2.5 System

Abiomed Mar 2015 PMA P140003 Temporary ventricular support for ≤6 h

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

RATIONALE

Summary of Evidence

Ventricular Assist Device (VAD)

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. The relevant outcomes are overall survival (OS), symptoms, functional outcomes, quality of life (QOL), 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 QOL. 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. The relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. A well-designed trial, with two years of follow-up data, has demonstrated an advantage of implantable VADs as destination therapy for patients ineligible for a heart transplant. Despite an increase in adverse events, both mortality and QOL 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 (TAH)

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

Percutaneous Ventricular Assist Device (pVAD)

For individuals with cardiogenic shock or who undergo high-risk cardiac procedures who receive a pVAD, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. The relevant outcomes are OS, symptoms, morbid events, functional outcomes, QOL, and treatment-related mortality and morbidity. Four RCTs of pVAD vs IABP for patients in cardiogenic shock failed to demonstrate a mortality benefit and reported higher complication rates with pVAD use. Comparative observational studies were consistent with the RCT evidence. RCTs, controlled and uncontrolled observational studies, and systematic reviews of these studies have not demonstrated a benefit of pVAD used as ancillary support for patients undergoing high-risk cardiac procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

SUPPLEMENTAL INFORMATION

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.

American College of Cardiology Foundation et al

The American College of Cardiology Foundation, American Heart Association (AHA), and Heart Failure Society of American (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 pVADs and extracorporeal VADs as nondurable MCS devices. Table 3 provides class IIA guidelines on MCS devices.

Table 3. 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 &quot;bridge to recovery&quot; or &quot;bridge to decision&quot; 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>

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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

The AHA (2012) published recommendations for the use of MCS. These guidelines defined nondurable MCS as intraballoon pumps, extracorporeal membrane oxygenation, extracorporeal VADs, and pVADs. Table 4 lists recommendations made on indications for the use of MCS, including durable and nondurable devices.

Table 4. 2012 Guidelines on MCS

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COE</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;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.&quot;</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>&quot;Implantation of MCS in patients before the development of advanced HF ... is associated with better outcomes. Therefore, early referral of HF patients is reasonable.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>&quot;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.&quot;</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.&quot;</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>&quot;These patients should be referred to a center with expertise in the management of durable MCS and patients with advanced HF.&quot;</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>&quot;Patients who are ineligible for heart transplantation because of pulmonary hypertension related to HF alone should be considered for bridge to potential transplant eligibility with durable, long-term MCS.&quot;</td>
<td>IIA</td>
<td>B</td>
</tr>
</tbody>
</table>
Heart Failure Society of America

Heart Failure Society of America (2010) published guidelines on surgical approaches to the treatment of heart failure. Table 5 lists recommendations on left VADs.

Table 5. 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>&quot;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.&quot;</td>
<td>B</td>
</tr>
<tr>
<td>&quot;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.&quot;</td>
<td>C</td>
</tr>
</tbody>
</table>

HF: heart failure; SOE: strength of evidence.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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 Food and Drug Administration (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 FDA for the bridge to transplant indication.
- The VAD is "used according to the FDA-approved labeling instructions."
- "The patient is approved 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:

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

Patient selection:
- New York Heart Association class IV end-stage left ventricular failure
- Not candidates for heart transplantation
- Failed to respond to optimal medical management,
- Left ventricular ejection fraction<25%, and,
- 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.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
48. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17;Tab 19.

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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New policy</td>
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<th>Date</th>
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<tbody>
<tr>
<td>December 2014</td>
<td>Replace policy</td>
<td>Policy updated with a literature review, adding references 5, 6, 20, 21, 24, 27, 28, 40-44, 47, 49, 50 &amp; 51 and deleting others. Policy updated to include total artificial hearts as medically necessary as a bridge to transplant for patients with biventricular failure until a donor can be obtained. The policy name was revised to add Total Artificial Hearts.</td>
</tr>
<tr>
<td>March 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 21, 2015; references 7-8, 27, 32, 38, 41, 50, 55, 57, 61-62, 65-66, and 70 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>March 2018</td>
<td>Archive policy</td>
<td>Policy updated with literature review through July 22, 2017; references 5-7, 34, 47, 49-51, 70, 72, 83, 85, 88, and 93 added. Policy statements were reordered; wording of statements unchanged. Policy archived.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Reactivate policy</td>
<td>Policy updated with literature review through June 21, 2018; several references added. Policy statements unchanged. Policy reactivated.</td>
</tr>
<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2019; references added. Regulatory Status section updated with HeartMate 3 indication for destination therapy. Policy statements unchanged except pVAD statement corrected to “not medically necessary” due to FDA PMA of Impella System.</td>
</tr>
</tbody>
</table>

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