Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Mechanical devices designed to assist or replace a failing heart have been developed over many decades of research. A ventricular assist device (VAD) is a mechanical support (pump), 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 (permanent) therapy in those who are not candidates for transplantation. The VAD has also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Policy

Implantable Ventricular Assist Devices

Implantable ventricular assist devices with U.S. Food and Drug Administration (FDA) approval or clearance may be considered medically necessary when used in accordance with device-specific, FDA-approved indications and contraindications for patients in the following situations:

- As a bridge to recovery for patients in the post-cardiotomy setting who are unable to be weaned off cardiopulmonary bypass
- As a bridge to heart transplantation for patients when the following criteria are met:
  - Survival is not expected until a donor heart can be obtained and one of the following:
    - Currently a candidate on the heart transplantation list
    - Evaluation to determine candidacy for heart transplantation is underway
- As destination therapy for patients with end-stage heart failure when both of the following criteria are met:
  - Evaluated and determined ineligible for human heart transplant for one or more of the following reasons:
    - Age > 65 years
    - Insulin dependent diabetes mellitus with end-organ damage
    - Chronic renal failure (serum creatinine > 2.5 mg/dL for ≥ 90 days)
    - Presence of other clinically significant condition (e.g., chronic irreversible hepatic, renal, or respiratory failure; systemic infection; coagulation disorders; life-limiting disease [cancer, neurologic damage, dialysis dependency]; uncorrected valvular disease; failure of medical compliance; chronic illicit drug or alcohol dependency; psychiatric condition leading to failure of medical compliance; inadequate psychosocial support)
  - One of the following “REMATCH Study” criteria:
    - New York Heart Association (NYHA) class IV heart failure for ≥ 60 days
    - NYHA class III/IV heart failure for 28 days, received ≥ 14 days' support with intra-aortic balloon pump or dependent on intravenous inotropic agents, with two failed weaning attempts

Implantable ventricular assist devices with FDA approval or clearance, including humanitarian device exemptions (HDE), may be considered medically necessary when used in accordance with device-specific, FDA-approved indications and contraindications as a bridge to heart transplantation in children when all of the following criteria are met:
• 16 years of age or younger
• Survival is not expected until a donor heart can be obtained and one of the following:
  o Currently a candidate on the heart transplantation list
  o Evaluation to determine candidacy for heart transplantation is underway

Other applications of implantable ventricular assist devices are considered investigational, including, but not limited to, the use of non-FDA approved or cleared implantable ventricular assist devices.

Percutaneous ventricular assist devices (pVADs) are considered investigational for all indications.

**Total Artificial Hearts**

Total artificial hearts with FDA-approved devices may be considered medically necessary when used in accordance with device-specific, FDA-approved indications and contraindications as a bridge to heart transplantation for patients with biventricular heart failure when all of the following criteria are met:

• There are no other reasonable medical or surgical treatment options
• Ineligible for other univentricular or biventricular support devices
• Currently a candidate on the heart transplantation list or are undergoing evaluation to determine candidacy for heart transplantation
• Survival is not expected until a donor heart can be obtained

Other applications of total artificial hearts are considered investigational, including, but not limited to:

• Use of total artificial hearts as destination therapy
• Use of non-FDA approved or cleared total artificial hearts

**Policy Guideline**

In general, candidates for bridge-to-transplant implantable ventricular assist devices (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 either of the following hemodynamic selection criteria:

• Left atrial pressure of 20 mm Hg
• 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 (UNOS) as Status I, that is, persons who are most ill and are considered the highest priority for transplant.

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

Individuals 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 individuals 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 (CT) scan.

New York Heart Association (NYHA) Classification (American Heart Association, 2011):

- **Class III**: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain
- **Class IV**: Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases

**Pediatric Ventricular Assist Devices (U.S. Food and Drug Administration [FDA] Inclusion and Exclusion Criteria for the Berlin Heart EXCOR® Pediatric VAD):**

- **Inclusion Criteria:**
  - Severe heart failure refractory to optimal medical therapy (New York Heart Association [NYHA] Functional Class IV for subjects ≤ 6 years) and has met at least one of the following criteria:
    - Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Patient Profile status 1 or 2
    - Pre-implant Extracorporeal Membrane Oxygenation (ECMO) or VAD
    - Failure to wean from cardiopulmonary bypass
  - Listed for cardiac transplantation
  - Two-ventricle circulation
  - Age 0-16 years
  - Weight 3-60 kilograms
  - Device must be FDA approved for this indication

- **Exclusion Criteria:**
  - Supported on ECMO ≥ 10 days
  - Cardiopulmonary Resuscitation (CPR) ≥ 30 minutes within 48 hours prior to device implantation
  - Mechanical aortic valve
  - Complex congenital or unfavorable anatomy
  - Irreversible non-cardiac end-organ damage
  - Documented heparin-induced thrombocytopenia (HIT) or coagulation disorder
  - Active infection
  - Life-limited disease
  - Stroke within past 30 days or congenital central nervous system (CNS) abnormality with risk of intra-cerebral bleeding
  - Psychiatric disease with a high likelihood for non-compliance
Coding

Effective in 2013, the following CPT codes were introduced:

- 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 transseptal puncture
- 33992: Removal of percutaneous ventricular assist device at separate and distinct session from insertion

The following CPT codes specifically describe total artificial hearts:

- 0051T: Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
- 0052T: Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)
- 0053T: Replacement or repair of implantable component or components of total replacement heart system (artificial heart), excluding thoracic unit

HCPCS code Q0505 will be deleted as of April 1, 2013 and will be replaced by the following HCPCS codes:

- Q0507: Miscellaneous supply or accessory for use with an external ventricular assist device
- Q0508: Miscellaneous supply or accessory for use with an implanted ventricular assist device
- Q0509: Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A

Removal of the device prior to heart transplantation (CPT codes 33977 and 33978) is considered part of the global fee and incidental to the heart transplant.

Ventricular Assist Devices and Total Artificial Hearts

Examples of Implantable Ventricular Assist Devices (VADs), Percutaneous Ventricular Assist Devices (pVADs), and Total Artificial Hearts (TAH) (not all inclusive):

<table>
<thead>
<tr>
<th>VAD Device</th>
<th>Manufacturer</th>
<th>Date of Initial Approval</th>
<th>Method of FDA Clearance</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoratec® Implantable VAD</td>
<td>Thoratec Corporation (Pleasanton, CA)</td>
<td>August 2004</td>
<td>PMA Supplement</td>
<td>Bridge to Transplant and Post-cardiotomy</td>
</tr>
<tr>
<td>DeBakey VAD® Child</td>
<td>MicroMed Cardiovascular, Inc. (Houston, TX)</td>
<td>April 2004</td>
<td>HDE</td>
<td>Bridge to Transplant in children 5 to 16 years of age</td>
</tr>
<tr>
<td>HeartMate II®</td>
<td>Thoratec Corporation (Pleasanton, CA)</td>
<td>April 2008</td>
<td>PMA</td>
<td>Bridge to Transplant and Destination</td>
</tr>
<tr>
<td>Device Name</td>
<td>Manufacturer</td>
<td>Date of Initial Approval</td>
<td>Method of FDA Clearance</td>
<td>Indication</td>
</tr>
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<tr>
<td><strong>Centrimag® Right Ventricular Assist Device</strong></td>
<td>Levitronix (Zurich)</td>
<td>October 2008</td>
<td>HDE</td>
<td>Post-cardiotomy</td>
</tr>
<tr>
<td><strong>Berlin Heart EXCOR® Pediatric VAD</strong></td>
<td>Berlin Heart, Inc. (Berlin, Germany)</td>
<td>December 2011</td>
<td>HDE</td>
<td>Bridge to Transplant in children younger than 5 years of age</td>
</tr>
<tr>
<td><strong>Impella</strong></td>
<td>AbioMed™ (Aachen, Germany)</td>
<td>May 2008</td>
<td>510(k)</td>
<td>Partial circulatory support using an extracorporeal bypass control unit for periods up to 6 hours</td>
</tr>
<tr>
<td><strong>TandemHeart™</strong></td>
<td>Cardiac Assist™ (Pittsburgh, PA)</td>
<td>September 2005</td>
<td>510(k)</td>
<td>Temporary left ventricular bypass of 6 hours or less</td>
</tr>
<tr>
<td><strong>SynCardia Temporary Total Artificial Heart</strong></td>
<td>SynCardia Systems, Inc. (Tucson, AZ)</td>
<td>October 2004</td>
<td>510(k)</td>
<td>Bridge to Transplant</td>
</tr>
<tr>
<td><strong>AbioCor® Implantable Replacement Heart System</strong></td>
<td>AbioMed, Inc. (Danvers, MA)</td>
<td>September 2006</td>
<td>HDE</td>
<td>Destination Therapy</td>
</tr>
</tbody>
</table>

**Documentation Required for Clinical Review**

- FDA approved implantable VAD or total artificial heart being requested
- History and physical and/or cardiac/transplant consultation report including:
  - Reason for implantable VAD or total artificial heart
  - NYHA functional class and duration of classification
  - Survival expectancy
  - Documentation that patient is on heart transplant list or undergoing evaluation to determine candidacy for heart transplantation
### Medical Policy: Implantable Ventricular Assist Devices and Total Artificial Hearts

**Original Policy Date:** 6/13/1997  
**Effective Date:** 3/29/2013

<table>
<thead>
<tr>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Reason patient is ineligible for heart transplantation (if applicable)</td>
</tr>
<tr>
<td>o Age of patient (if requesting pediatric implantable VAD)</td>
</tr>
<tr>
<td>o Hospital progress notes including documentation of current and past treatment(s) and response to treatment(s) including future medical/surgical treatment options</td>
</tr>
<tr>
<td>o Documented ineligibility for other univentricular or biventricular support devices</td>
</tr>
</tbody>
</table>

### Post Service
- Operative procedure report(s) (if applicable)

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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.