HEART TRANSPLANTATION

Policy Number: 2015M0048A       Effective Date: July 1, 2015

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of heart transplantation, the act of surgically removing the diseased heart of a patient and replacing it with a healthy heart graft from a recently deceased or brain dead donor, also called a beating heart cadaver (cadaveric allograft).

Heart transplantation is not considered a cure for heart disease, but may be a lifesaving procedure for patients with end-stage heart failure or severe coronary artery disease when there are no alternative treatment options. Prolonged survival and improved quality of life are the major goals of heart transplantation. The success of heart transplantation is directly related to the severity of illness; when patients are critically ill prior to transplant, the outcome is likely to be worse than for patients who are not as ill. The challenge for the transplant team is to choose their candidates wisely to optimize the scarce supply of donor organs and to transplant early enough in the patient’s illness to assure a good chance for recovery.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

I. Heart Transplantation

Heart transplantation is considered **MEDICALLY NECESSARY** for individuals with ANY of the following indications (not an all-inclusive list):

- Recurrent life-threatening arrhythmias unresponsive to medical and/or surgical therapy
- Congenital heart disease not amenable to surgical correction or that has failed previous surgical correction
- End-stage ventricular failure with severe cardiac disability despite optimal medical therapy, New York Heart Association functional class III or IV, and objective evidence of impaired functional capacity (peak oxygen consumption <14 mL/kg/min)
- Refractory heart failure requiring continuous inotropic (medications that support cardiac muscle contraction) support
- End-stage Idiopathic dilated cardiomyopathy unresponsive to medical therapy, when the individual has developed severe ventricular dysfunction or other nonoperable late-term complications
- Inability to be weaned from temporary cardiac-assist devices after myocardial infarction or non-transplant cardiac surgery
- Intractable angina with coronary artery disease on an individual with a New York Heart Association functional class III or IV, not amenable to revascularization.
- Myocarditis that has failed to improve with conventional therapy
- Severe hypertrophic or restrictive cardiomyopathy, with NYHA Class IV symptoms
- Valvular heart disease with left ventricular dysfunction (not correctable with valve replacement or repair)
- Primary cardiac dysplasia/tumors confined to the myocardium, with a low likelihood of metastasis at time of transplantation
II. Heart Retransplantation

Heart retransplantation may be considered MEDICALLY NECESSARY due to primary graft failure, rejection refractory to immunosuppressive therapy and graft coronary artery disease with severe ischemia of the heart graft.

Note: Retransplantation appears most appropriate for those patients more than 6 months following original heart transplantation, who have severe cardiac allograft vasculopathy and associated left ventricular dysfunction, or allograft dysfunction and progressive symptoms of heart failure in the absence of acute rejection.

III. Ventricular Assist Devices (VAD)

- Food and Drug Administration (FDA)-approved VAD may be considered MEDICALLY NECESSARY as a bridge to transplant for members who are awaiting heart transplantation.
- FDA-approved pediatric VADs may be considered MEDICALLY NECESSARY when a child has documented end-stage left ventricular failure and an age appropriate VAD will be used until a donor heart can be obtained.
- FDA-approved VAD as destination therapy may be considered MEDICALLY NECESSARY when all of the following criteria are met:
  - Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not a candidate for heart transplant
  - Member has failed to respond to optimal medical management for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or has been IV inotrope dependent for 14 days
  - Has a left ventricular ejection fraction (LVEF) less than 25 %
  - Has demonstrated functional limitation with a peak oxygen consumption

IV. Total Artificial Heart

- Food and Drug Administration-approved total artificial heart (e.g., CardioWest Total Artificial Heart, SynCardia Systems, Tucson, AZ) may be considered MEDICALLY NECESSARY when used as a bridge to transplant for transplant eligible members who are at imminent risk of death (NYHA Class IV) due to biventricular failure who are awaiting heart transplantation.
- The use of a total artificial heart (e.g., ABIOCOR Total Artificial Heart, CardioWest Total Artificial Heart) as permanent treatment (destination therapy, as an alternative to heart transplantation) is considered INVESTIGATIONAL AND/OR EXPERIMENTAL because its safety and effectiveness for this indication has not been established.

V. Xenotransplantation

Xenotransplantation of solid organ (e.g., porcine xenografts) is considered INVESTIGATIONAL AND/OR EXPERIMENTAL because its safety and/or effectiveness has not been established.

VI. Breath Test for Heart Transplant Rejection

The Heartsbreath Test (Menassana Research, Inc, Fort Lee, NJ) is considered INVESTIGATIONAL AND/OR EXPERIMENTAL for diagnosing heart transplant rejection and for all other indications because its clinical value has not been established.
VII. Allomap™ Molecular-Expression Blood Test

The Allomap™ gene expression profile may be considered **MEDICALLY NECESSARY** for monitoring rejection in heart transplant recipients more than 1 year post-heart transplant.

The Allomap™ gene expression profile is considered **INVESTIGATIONAL AND/OR EXPERIMENTAL** for all other indications because its clinical value has not been established.

Clinical Considerations:

- **Minimum patient evaluation requirements:**
  1. Assessment of heart failure severity
     - EKG
     - Echocardiogram
     - Cardiopulmonary stress test
     - Right heart catheterization
     - VO2 max
  2. Liver function tests (LFT) with transaminases ≤ 3x upper limit of normal and total bilirubin < 2.5mg/dl.
  3. HbA1C for diabetics.
  4. Serum creatinine < 2.5 mg/dl (≤ 1.5 mg/dl in children) or GFR > 35 ml/min due to intrinsic renal disease or not reversible with augmentation of cardiac output. If abnormal, may be eligible for a combined transplant.
  5. Carotid Doppler ultrasound when indicated or age > 50 – Abnormal findings evaluated further. Intervention and/or clearance required for abnormal findings.

- **Member has a New York Heart Association (NYHA) class III or IV for heart failure:**
  - Class III: Persons with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain.
  - Class IV: Persons with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the angina syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

  **Note:** does not apply to pediatric members

- **Member has potential for conditioning and rehabilitation after transplant (e.g., member is not moribund)**
- **Life expectancy (in the absence of cardiovascular disease) is greater than 2 years**
- **No malignancy (except for non-melanomatous skin cancers) or malignancy has been completely resected or (upon individual case review) malignancy has been adequately treated with no substantial likelihood of recurrence with acceptable future risks**
- **Adequate pulmonary, liver and renal function. Patients with renal/lung failure should be evaluated for combined heart-lung or heart-kidney transplantation**
- **Absence of diabetes with severe end-organ damage (neuropathy, nephropathy with declining renal function and proliferative retinopathy)**
• No uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen
• No active alcohol or chemical dependency that interferes with compliance to a strict treatment regimen
• Patients over the age of 70, high dose systemic corticosteroid use (> 10mg prednisone/day or equivalent), or BMI < 20 or > 30 kg/ m² must be referred to the Medical Director

Contraindications:
• Malignancy that is expected to significantly limit future survival
• Systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery (e.g., autoimmune, collagen vascular disease)
• Presence of irreversible end-organ diseases (e.g., renal, hepatic, pulmonary), unless person is to undergo dual organ transplantation (e.g., heart-lung, heart-kidney, etc.)
• Presence of severe pulmonary hypertension with irreversibly high pulmonary vascular resistance
• Presence of a recent intra-cranial cerebrovascular event with significant persistent deficit
• A pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure
• Presence of bleeding peptic ulcer or diverticulitis
• Presence of life-threatening neuromuscular disorders
• Persistent, recurrent or unsuccessfully-treated major or systemic infections
• Presence of hepatitis B antigen
• Human immunodeficiency virus (HIV) disease unless all of the following are noted:
  o CD4 count greater than 200 cells/mm³
  o HIV-1 ribonucleic acid (RNA) undetectable
  o Stable anti-retroviral therapy for more than three months
  o Absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections; or Kaposi’s sarcoma or other neoplasm)

BACKGROUND:
Heart transplantation is a widely accepted therapy for the treatment of end-stage cardiac disease. About 2,000 heart transplants are performed each year in the United States and approximately 20,000 people now live with a transplanted heart. Survival rates have improved with the advent of newer immunosuppressive agents (tacrolimus and mycophenolate). Survival is nearly 90% at 1 year, 75.0% at 5 years, and the median survival is more than 10 years. It has been projected that patients who receive cardiac transplants have an in-hospital mortality rate of less than 5 %. Moreover, 90 % of cardiac transplant patients lead a relatively normal lifestyle having no limitations in their activity and 40 % return to work. Infant heart recipients (less than one year old) had poor survival rates during the first post-transplant year (74% compared to > 85% for all other age groups), but those who survived had better long-term outcomes than adults. Moreover, survival in children with dilated cardiomyopathy relies on accurate diagnosis and aggressive treatment. Elderly recipients (aged 65 or older) had survival rates comparable to younger
patients through about 8 years, when survival rates began to fall more rapidly.” In spite of these statistics, the long-term success of cardiac transplants still has room for improvement.

In adults, cardiac transplantation is most frequently performed for patients with cardiomyopathy (about 50%), coronary artery disease (about 40%), valvular disease (about 4%), re-transplantation following a failed primary transplantation (about 2%) and congenital heart disease (about 2%).

In children, the most common indications for cardiac transplantation are congenital heart disease (about 47%), dilated cardiomyopathy (about 45%), and retransplantation (about 3%).

Cardiac transplantation is currently the only proven curative treatment for end stage heart disease, but the supply of donor hearts has not kept pace with the demand. Cardiac transplant waiting lists have the highest mortality (30%) of any solid organ waiting list. Survival after transplantation is good, with an intermediate survival rate of about 70%.

Therefore, surgical techniques such as reduction ventriculoplasty, transmyocardial laser revascularization, myoreduction or remodeling operations (Batista operation) and surgical ventricular restoration (Dor Procedure) or dynamic cardiomyoplasty are employed to maintain heart function or provide a bridge to heart transplantation. The literature indicates that patients may respond to these treatments for heart failure or may deteriorate, requiring mechanical support. Extracorporeal membrane oxygenation has been used effectively for mechanical support in children until improvement occurs or as a bridge to transplantation. In addition, ventricular assist devices and the total artificial heart have been approved by the Food and Drug Administration (FDA) for use as a bridge to transplant in selected persons who are awaiting heart transplantation.

**Ventricular Assist Devices (VADs):** As patients become more hemodynamically compromised, there is an increased risk of death prior to transplantation, as well as a less favorable outcome following transplantation. External or implantable ventricular assist devices (VADs) are therefore used for many patients with end-stage heart failure while awaiting transplantation. Timely use of VADs may be successful in preventing further deterioration and reversing metabolic, cellular and nutritional compromise. The temporary use of these mechanical devices is referred to as “bridging” to transplant. VADs are usually inadequate as a bridge to transplant for patients with severe biventricular disease, and two paracorporeal devices may be needed. VADs may be contraindicated, however, in those with aortic regurgitation, cardiac arrhythmias, left ventricular thrombus, aortic prosthesis, acquired ventricular septal defect, or irreversible biventricular failure. A total artificial heart (TAH) is a mechanical circulatory device that has been used primarily to maintain patients until a suitable donor heart is available for transplantation. VADs and biventricular assist devices may also be considered as a permanent cardiac replacement, or “destination therapy”, for patients with end-stage heart disease who are not candidates for heart transplantation. The HeartMate II and The HeartWare Left Ventricular Assist Devices (LVADs) LVAS account for a large majority of LVADs implanted.

**Total Artificial Heart (TAH):** A total artificial heart can maintain the life of a patient with an irreparably damaged heart. The proportion of patients receiving a heart transplant with a mechanical circulatory support device (MCSD) in place at the time of transplant has risen to > 42% according to the July 2012 report from the Scientific Registry of Transplant recipients (SRTR).

The New York Heart Association (NYHA) classification of heart failure is one of the many parameters used for selecting heart recipients. It is a 4-tier system that categorizes patients based on subjective impression.
of the degree of functional compromise. The 4 NYHA functional classes are as follows:

Class I: Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. Symptoms only occur on severe exertion.

Class II: Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest but ordinary physical exertion, such as carrying shopping bags up several flights or stairs results in fatigue, palpitation, dyspnea, or anginal pain.

Class III: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) 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 cardiac insufficiency or of the angina syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Allomap™ Molecular Expression for Detection of Heart Transplant Rejection

Although long-term outcomes of cardiac transplantations have steadily improved, numerous life-threatening complications persist, including infection, allograft rejection, and allograft vascular disease. Allograft rejection is most frequent within the first month following transplantation and declines progressively thereafter. Endomyocardial biopsy is currently the standard for detecting allograft rejection after heart transplantation. Typically, the patient will have biopsies to monitor for rejection weekly for the first 4 to 6 weeks after transplantation, biweekly until the third month, monthly to 6 months, and then every 1 to 3 months as indicated. However, as endomyocardial biopsies are invasive and have several limitations, alternative noninvasive techniques to detect and monitor allograft rejection, including molecular expression testing, are under investigation. A summary of the available data on analytical validity indicates that the Allomap™ test is reproducible and has precision that is appropriate for its role in the detection of cardiac allograft rejection. The Allomap™ assay is FDA approved and the test is performed in a laboratory, which has current CLIA certification.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   - **Berlin Heart EXCOR Pediatric Ventricular Assist Device.** This device is available in a number of sizes for pediatric patients (children aged 16 years or younger). This device was FDA approved in December 2011.
   - **HeartAssist 5® Pediatric Ventricular Assist Device:** This device is available in a number of sizes for pediatric patients (for children aged 5 to 16 years).
   - **The HeartMate II:** This is a continuous flow device, approved by FDA for use as both Bridge to Transplant (BTT) and as Destination Therapy (DT). This is one of only two devices that are currently FDA approved for DT. The other device is the HeartMate I, a pulsatile flow device that is rarely used since the approval of the HeartMate II.
     The HeartMate II received FDA approval for BTT and DT on April 2008 and January 2010 respectively.
   - **The HeartWare® Ventricular Assist Device:** The U.S. Food and Drug Administration on Nov. 20,
2012 approved the HeartWare Ventricular Assist System, a left ventricular assist device (LVAD), to support heart function and blood flow in patients with end-stage heart failure who are awaiting a heart transplant. Given that this device is totally implantable within the pericardial sac with no need for an abdominal pocket it is anticipated to increase in utilization.

- **SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ):** The SynCardia temporary Total Artificial Heart, formerly referred to as the CardioWest™ Total Artificial Heart, received FDA premarket approval (PMA) on October 15, 2004 as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The FDA approval states that the temporary TAH is intended to be used inside the hospital. The CardioWest TAH is a biventricular, pneumatic pulsatile blood pump that fully replaces the patient’s ventricles and all four cardiac valves.

  In the U.S., the Syncardia TAH is powered by a large console on wheels that requires inpatient hospitalization, although in Europe, portable drivers are may be used.

- **The Freedom Driver:** The Freedom Driver has recently been approved for use under a clinical trial in the United States. This allows patients with the TAH to be discharged home pre-transplant for the first time. This device is used as BTT for patients with severe right heart failure in addition to left heart failure.

- **AbioCor® Implantable Replacement Heart (IRH) (ABIOMED™, Inc., Danvers, MA):** The AbioCor IRH is an artificial heart with completely internal components designed to provide circulatory control in order to prolong life and provide an acceptable quality of life. The internal components of the AbioCor system consist of the thoracic unit, implanted controller, implanted battery, and implanted transcutaneous energy transfer (TET) coil. The external components include the console and patient-carried electronics. The controller monitors and controls functioning of the device, including the pumping rate of the heart. The internal battery allows the recipient to be free from all external connections for up to one hour. The system also includes two external batteries that allow up to two hours of freedom of movement. When the patient is sleeping, or when the batteries are being recharged, the system is plugged into an electrical outlet (Samuels and Dowling, 2003; U.S. FDA, 2006).

  The AbioCor IRH received FDA Humanitarian Device Exemption (HDE) approval on September 5, 2006, for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who:

  - Are less than 75 years old
  - Require multiple inotropic support
  - Are not treatable by LVAD destination therapy, and
  - Are not weanable from biventricular support, if on such support

  The FDA Summary of Safety and Probable Benefit includes the following contraindications:

  - Presence of other irreversible end organ dysfunction that would compromise survival
  - Inadequate psychosocial support
  - Preoperative noninvasive anatomical assessment indicating inadequate fit (i.e. Thoracic volume is unable to accommodate the device)
  - Presence of coagulation disorders
• **Allomap™**: The molecular expression assay received FDA approval on August 26, 2008, as an In Vitro Diagnostic Multivariate Index Assay (IVDMIA) (CDRH, 2008; XDx Inc., 2008). Prior to formal FDA approval, Allomap™ was available under the Clinical Laboratory Improvement Amendments (CLIA) from its launch in January 2005 (XDx Inc., 2008). It is indicated for use in adult cardiac transplant patients with stable allograft function who have a low probability of moderate/severe acute cellular rejection at the time of testing, are 15 years or older, and are at least 2 months (55 days) post transplant. XDx has CLIA certification (XDx Inc., 2011a).

• **Heartsbreath Test**
  Menssana Research, Inc. (Fort Lee, NJ) received a FDA humanitarian device approval for the Heartsbreath Test on February 2004, for evaluation of heart transplant rejection. According to the FDA-approved product labeling, the product is to be used as an aid in diagnosis of grade 3 heart transplant rejection in patients who have received heart transplants within the preceding year (FDA, 2004). The labeling states that the Heartsbreath test is intended to be used as an adjunct to, and not as a substitute for endomyocardial biopsy. The labeling states that the use of the Heartsbreath Test is limited to patients who have had endomyocardial biopsy within the previous month.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

   **Heart Transplants (NCD 260.9)**
   Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See CMS Ruling 87-1.)

   **Exceptions**
   In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than 2 years, and applications from consortia will not be approved.

   Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:

   • The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally constituted medical research institute; and
   
   • The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same personnel and services in all of the individual hospitals. At a minimum, shared resources means:
     
     • The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and
     
     • The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals; and
     
     • The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and
• The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

**Pediatric Hospitals**

Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which CMS approves as documenting that:

- The hospital’s pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1;
- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

**Follow-Up Care**

Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions From Coverage,” §180.)

**Immunosuppressive Drugs**

See the Medicare Claims Processing Manuals, Chapter 17, “Drugs and Biologicals,” §§80.3.1 and, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §120.1.

**Artificial Hearts**

Medicare covers ventricular assist devices (VAD) and artificial hearts when implanted under the coverage criteria stated in §20.9 of the manual (NCD Manual 100-03).

**Heartsbreath Test.**

On December 8, 2008, the Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum (CAG-00394N) in response to a formal request for Menssana Research, Inc., to consider national coverage of the Heartsbreath test as an adjunct to the heart biopsy to detect grade 3 heart transplant rejection in patients who have had a heart transplant within the last year and an endomyocardial biopsy in the prior month. The CMS determined that the evidence does not adequately define the technical characteristics of the test nor demonstrate that Heartsbreath testing to predict heart transplant rejection improves health outcomes.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

MHCP coverage for organ and tissue transplant procedures is limited to those procedures covered by the Medicare program or approved by the DHS consulting contractor. Transplant coverage includes: preoperative evaluation, recipient and donor surgery, follow-up care for the recipient and live donor, and retrieval of organs, tissues. All transplant related services are billed under the recipient’s ID number.
**CLINICAL EVIDENCE:**

**SUMMARY:**

Heart transplantation has become the standard treatment for eligible patients with irreversible biventricular failure unresponsive to medical treatment. The supply of donor hearts has decreased in recent years, however, while the demand has increased significantly. External or implantable ventricular assist devices (VADs) are therefore used for many patients with end-stage heart failure while awaiting transplantation. VADs may be contraindicated, however, in those with aortic regurgitation, cardiac arrhythmias, left ventricular thrombus, aortic prosthesis, acquired ventricular septal defect, or irreversible biventricular failure. A total artificial heart (TAH) may be used to maintain patients until a suitable donor heart is available for transplantation, when VADs and biventricular assist devices are contraindicated. There is adequate evidence to demonstrate that the SynCardia temporary Total Artificial Heart (SynCardia Systems, Inc., Tucson, AZ) is a relatively safe and effective bridge to transplantation in carefully selected heart transplant candidates who are at risk of imminent death due to biventricular failure.

The AbioCor® Implantable Replacement Heart (IRH) (Abiomed™ Inc., Danvers, MA) received a U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) in 2006. The AbioCor IRH may be a treatment option for carefully selected patients with severe biventricular end-stage heart disease who are not cardiac transplant candidates, are less than 75 years old, require multiple inotropic support, are not treatable by left ventricular assist device (LVAD) destination therapy, and are not weanable from biventricular support, if on such support.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>S2152</td>
<td>Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and post-transplant care in the global definition</td>
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<tr>
<th>ICD-9 Codes</th>
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<td>Amyloidosis</td>
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<td>Progressive angina pectoris</td>
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<td>Hypertrophic cardiomyopathy</td>
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**ICD-10 Codes**

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<td>I20.0</td>
<td>Unstable angina</td>
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<td>I25.1-125.9</td>
<td>Chronic ischemic heart disease</td>
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<td>Cardiomyopathy in diseases classified elsewhere</td>
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<tr>
<td>B33.24</td>
<td>Viral cardiomyopathy</td>
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<tr>
<td>I50.1-I50.9</td>
<td>Heart failure</td>
</tr>
<tr>
<td>I51.4</td>
<td>Myocarditis, unspecified</td>
</tr>
<tr>
<td>Q20-Q28.9</td>
<td>Congenital malformations of the circulatory system</td>
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<tr>
<td>090.3</td>
<td>Peripartum cardiomyopathy</td>
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<tr>
<td>I42.8</td>
<td>Other cardiomyopathies</td>
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</tbody>
</table>

**CPT® Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0051T</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiecatomy</td>
</tr>
<tr>
<td>0052T</td>
<td>Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)</td>
</tr>
<tr>
<td>0053T</td>
<td>Replacement or repair of implantable component or components of total replacement heart system (artificial heart) excluding thoracic unit</td>
</tr>
<tr>
<td>33930</td>
<td>Donor cardiectomy-pneumonectomy (including cold preservation)</td>
</tr>
<tr>
<td>33933</td>
<td>Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation</td>
</tr>
<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
</tr>
<tr>
<td>33940</td>
<td>Donor cardiectomy (including cold preservation)</td>
</tr>
<tr>
<td>33944</td>
<td>Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation</td>
</tr>
<tr>
<td>33945</td>
<td>Heart transplant, with or without recipient cardiectomy</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>
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<tr>
<td>33977</td>
<td>Removal of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td>33978</td>
<td>Removal 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>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>
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<td>33992</td>
<td>Removal of percutaneous ventricular assist device at separate and distinct session from insertion</td>
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<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>

CPT® is a registered trademark of the American Medical Association.
REFERENCES:


3. AHA. American Heart Association. Available at: [http://my.americanheart.org/professional/StatementsGuidelines/ByPublicationDate/PreviousYears/Classification-of-Functional-Capacity-and-Objective-Assessment_UCM_423811_Article.jsp](http://my.americanheart.org/professional/StatementsGuidelines/ByPublicationDate/PreviousYears/Classification-of-Functional-Capacity-and-Objective-Assessment_UCM_423811_Article.jsp). Accessed January 03, 2014.


9. Canter CE. Indications for heart transplantation in pediatric heart disease: a scientific statement from the American Heart Association Council on Cardiovascular Disease in the Young; the Councils on Clinical Cardiology, Cardiovascular Nursing, and Cardiovascular Surgery and Anesthesia; and the Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation - 6-FEB-2007; 115(5): 658-76


17. Copeland JG, Smith RG, Arabia FA, Nolan PE, Mehta VK, McCarthy MS, Chisholm KA. Comparison of the
CardioWest total artificial heart, the Novacor left ventricular assist system and the Thoratec ventricular assist system in bridge to transplantation. Ann Thorac Surg. 2001 Mar;71(3 Suppl):S92-7; discussion S114-5.


## POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>01/23/2014</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>02/01/2014</td>
<td>Published to UCare.org</td>
</tr>
<tr>
<td>07/01/2015</td>
<td>Policy Update:</td>
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<tr>
<td></td>
<td>• Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.</td>
</tr>
<tr>
<td></td>
<td>• Policy identification number updated to 2015M0048A.</td>
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