VENTRICULAR ASSIST DEVICES
AND TOTAL ARTIFICIAL HEARTS

Description: Ventricular Assist Devices
A ventricular assist device (VAD) is a mechanical pump that provides circulatory support in patients whose hearts can no longer pump blood effectively due to heart failure. VADs may be used as a bridge to transplantation or as destination therapy in patients who are not candidates for heart transplantation. More recently, VADs have also been used as a bridge to recovery in patients with reversible conditions affecting cardiac output.

Ventricular assist devices 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. Continuous axial flow devices are smaller in size and have other technical advantages over pulsatile models.

A variety of implantable devices have received approval for marketing from the U.S. Food and Drug Administration (FDA), encompassing biventricular and right and left ventricular devices, as well as devices that are intended to be used in the hospital setting alone and those that can be used in an outpatient setting.

Percutaneous ventricular assist devices (pVADs) have been developed for short-term use in patients who require acute circulatory support and have been proposed for use in the following situations: 1) cardiogenic shock that is refractory to medications and use of an intra-aortic balloon pump (IABP), 2) cardiogenic shock, as an alternative to IABP, and 3) high-risk patients undergoing invasive cardiac procedures who need circulatory support. Two different pVADs have been developed and cleared for marketing through the U.S. Food and Drug Administration (FDA):
the TandemHeart™ (Cardiac Assist™), and the Impella® (AbioMed™).

**Total Artificial Hearts**
The total artificial heart is a pulsating bi-ventricular device that is implanted into the chest to replace the individual's left and right ventricles. This device provides a bridge to transplantation for individuals who have no other reasonable medical or surgical treatment options.

In 2004, the CardioWest Total Artificial Heart received FDA approval as a bridge to transplantation. In 2006, the FDA approved the first totally implanted artificial heart, the AbioCor Implantable Replacement Heart, for patients with advanced heart failure involving both pumping chambers of the heart. This device was approved under the Humanitarian Use Device (HUD) provision.

**Definitions:**
New York Heart Association (NYHA) Functional Classification:
Class I - No limitation of physical activity.
Class II - Slight limitation of physical activity.
Class III - Marked limitation of physical activity
Class IV - Unable to carry out any physical activity.

**Policy:**
I. **Implantable Ventricular Assist Devices**
   A. Implantable ventricular assist devices with FDA approval may be considered MEDICALLY NECESSARY as a bridge to recovery in patients with a potentially reversible condition, including but not limited to:
      1. Cardiogenic shock;
      2. Cardiomyopathy;
      3. Myocarditis;
      4. Following cardiac surgery when the patient cannot be weaned from cardiopulmonary bypass.
   B. Implantable ventricular assist devices with FDA approval may be considered MEDICALLY NECESSARY as a bridge to heart transplantation in adults who meet one of the following criteria:
      1. The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; OR
      2. The patient is undergoing evaluation to determine candidacy for heart transplantation.
   C. Implantable ventricular assist devices with FDA approval, including humanitarian device exemptions, may be considered MEDICALLY NECESSARY as a bridge to heart transplantation in children and adolescents who meet one of the following criteria:
      1. The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; OR
2. The patient is undergoing evaluation to determine candidacy for heart transplantation.

D. Implantable ventricular assist devices with FDA approval may be considered **MEDICALLY NECESSARY** as destination therapy in patients with end-stage heart failure who are ineligible for heart transplantation and who meet one of the following criteria:

1. Symptoms of New York Heart Association (NYHA) class IV heart failure for \( \geq 60 \) days; OR
2. Symptoms of NYHA class III/IV for at least 28 days and dependent on intra-aortic balloon pump for \( \geq 14 \) days or IV inotropic agents, with two failed weaning attempts.

II. **Percutaneous Ventricular Assist Devices**

A. Percutaneous ventricular assist devices (pVADs) are considered **INVESTIGATIVE** for all indications, due to a lack of evidence demonstrating an impact on improved health outcomes.

III. **Total Artificial Hearts**

A. Total artificial hearts, used in accordance with their FDA approval, may be considered **MEDICALLY NECESSARY** as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

B. All other applications of total artificial hearts are considered **INVESTIGATIVE**, including but not limited to, the use of total artificial hearts as destination therapy.

**Coverage:**

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member’s summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if
criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:**

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT:**

33975 Insertion of ventricular assist device, extracorporeal, single ventricle
33976 Insertion of ventricular assist device, extracorporeal, biventricular
33979 Insertion of ventricular assist device, implantable, intracorporeal, single ventricle
33981 Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982 Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983 Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
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
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

**ICD-9 Procedure:**

37.41 Implantation of Prosthetic cardiac support device around the heart
37.52 Implantation of total internal biventricular heart replacement system
37.53 Replacement or repair of thoracic unit of (total) replacement heart system
37.54 Replacement or repair of other implantable component of (total) replacement heart system
37.55 Removal of internal biventricular heart replacement system
37.60 Implantation or insertion of biventricular external heart assist system
37.62 Insertion of temporary non-implantable extracorporeal circulatory assist device
37.63 Repair of heart assist system
37.64 Removal of external heart assist system(s) or device(s)
37.65 Implant of external heart assist system
37.66 Insertion of implantable heart assist system
37.67 Implantation of cardiomyostimulation system
37.68 Insertion of percutaneous external heart assist device

**ICD-10 Procedure:**
02UA0JZ Supplement Heart with Synthetic Substitute, Open Approach
02RK0JZ Replacement of Right Ventricle with Synthetic Substitute, Open Approach
02WA0JZ Revision of Synthetic Substitute in Heart, Open Approach
02WA0QZ Revision of Implantable Heart Assist System in Heart, Open Approach
02PA0QZ Removal of Implantable Heart Assist System from Heart, Open Approach
02HA0RS Insertion of Biventricular External Heart Assist System into Heart, Open Approach
5A02216 Assistance with Cardiac Output using Other Pump, Continuous
02WA4QZ Revision of Implantable Heart Assist System in Heart, Percutaneous Endoscopic Approach
02PA0RZ Removal of External Heart Assist System from Heart, Open Approach
02HA0RZ Insertion of External Heart Assist System into Heart, Open Approach
02HA0QZ Insertion of Implantable Heart Assist System into Heart, Open Approach
02HN4MZ Insertion of Cardiac Lead into Pericardium, Percutaneous Endoscopic Approach

**Deleted Codes:** 0048T, 0049T

**Policy History:**
Developed November 12, 2008 (Combined policies)
Most recent history:
Revised January 12, 2011
Cross Reference: Humanitarian Use Devices, IV-11
Organ Transplantation, IV-128

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