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Subject: Total Artificial Hearts and Implantable Ventricular Assist Devices

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DESCRIPTION:

Heart failure may be the consequence of a number of differing etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and survival; however, the number of candidates for transplant exceeds the supply of donor organs, thus compelling the development of mechanical devices.

The New York Heart Association (NYHA) developed a functional classification for heart disease. Each of the four classifications are described in the table below:

Class I (mild)	Has no limitations on clinical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (mild)	Has slight limitations of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (moderate)	Has marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Ventricular Assist Devices

Implantable ventricular assist devices are attached to the native heart, which may have enough residual activity to withstand a device failure in the short term. In reversible conditions of heart failure, 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 flow devices may move blood in rotary or axial flow.

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 recipient 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).

Percutaneous Ventricular Assist Devices

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). These may be referred to as pVADs. pVADs are placed through the femoral artery.

Total Artificial Hearts

The total artificial heart (TAH) is a biventricular device which completely replaces the function of the diseased heart. An internal battery requires 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 heart must be removed, failure of the device is synonymous with cardiac death.

Summary and Analysis of Evidence: An UpToDate review titled "Treatment of advanced heart failure with a durable mechanical circulatory support device" (Birks et al) states "The long-term survival of patients who undergo durable MCS device placement is dependent on the patient's characteristics at implant, whether the patient remains eligible for transplant, and the type of device. For those with a ventricular assist device, in a randomized trial that compared the HeartMate III device with the HeartMate II device, five-year survival free of a major stroke in the HeartMate III group was 58 percent. In a large registry (INTERMACS) that included patients with ventricular assist device (VAD) support, patients with an initial bridge to transplantation or bridge to candidacy implant strategy had five-year survival of 52 and 51 percent, respectively, and patients with an initial destination therapy strategy had a five-year survival of 44 percent. In those with an artificial heart, outcomes are worse with artificial hearts than with LV assist devices (LVADs), but in some patients with biventricular failure, an artificial heart may be the only option for durable MCS. In a large registry (INTERMACS) that included patients with artificial heart support and that reported outcomes up to two years after implant, 34 percent of patients died, 53 percent had undergone heart transplantation, and 13 percent were alive with their device in place. The complications of durable MCS include stroke, major bleeding, major infection,

device malfunction/pump thrombosis, and right HF. The risk of complications is based on patient risk factors, long-term management of the patient, and characteristics of specific devices."

POSITION STATEMENT:

Ventricular Assist Devices

The use of an FDA-approved or cleared [including Humanitarian Device Exemption (HDE)] implantable ventricular assist device (VAD), **meets the definition of medical necessity:**

- As a **bridge to heart transplantation** for adults or children who:
  - Are currently listed as heart transplant candidates, **OR**
  - Are undergoing evaluation to determine candidacy for heart transplant, **AND**
  - Are not expected to survive until a donor heart can be obtained
- As a **bridge to recovery** in the post-cardiotomy setting in members who are unable to be weaned off cardiopulmonary bypass.
- As **destination therapy** when the following criteria are met:
  - New York Heart Association (NYHA) Class III heart failure with dyspnea upon mild physical activity or NYHA Class IV
  - Left ventricular ejection fraction ≤ 25%
  - Inotrope-dependent, **OR** cardiac index <2.2 liters/min/m2, while not on inotropes and also meeting **ONE** of the following:
    - On optimal medical management, based on current heart failure practice guidelines for at least 45 of the last 60 days and are failing to respond, **OR**
    - Advanced heart failure for at least 14 days and dependent on intra-aortic balloon pump for ≥7 days

The use of an FDA-approved or cleared [including Humanitarian Device Exemption (HDE)] percutaneous ventricular assist device **meets the definition of medical necessity** to provide short term circulatory support for**:**

- Cardiogenic shock, **OR**
- Acute myocardial infarction, **OR**
- High risk percutaneous coronary interventions (PCI)

The use of an FDA-approved or cleared [including Humanitarian Device Exemption (HDE)] right ventricular assist device **meets the definition of medical necessity** when both of the following are met:

- Device is used for temporary circulatory support for up to thirty days for individuals in cardiogenic shock due to acute right ventricular failure, **AND**
- Member is willing and able to be treated with heparin or an appropriate alternative anticoagulant

Total Artificial Hearts

The use of an FDA-approved or cleared [including Humanitarian Device Exemption (HDE)] total artificial heart **meets the definition of medical necessity** as a bridge to transplantation when all of the following are met:

- Biventricular failure with no other reasonable medical or surgical treatment options, **AND**
- Ineligible for other univentricular or biventricular support devices, **AND**
- Currently listed as a heart transplant candidate or undergoing evaluation to determine candidacy for heart transplant, **AND**
- Not expected to survive until a donor heart can be obtained

Other applications of implantable ventricular devices or total artificial hearts, including the use of total artificial hearts as destination therapy, are considered **experimental or investigational**. There is insufficient clinical evidence in the peer reviewed literature to allow conclusions on health outcomes.

Accessories and supplies used with a mechanical circulatory assist device **meet the definition of medical necessity** when criteria for the mechanical circulatory assist device are met.

BILLING/CODING INFORMATION:

CPT Coding:

33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)
33975	Insertion of ventricular assist device; extracorporeal, single ventricular
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33977	Removal of ventricular assist device; extracorporeal single ventricular
33978	Removal of ventricular assist device; extracorporeal biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal 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; left heart, arterial access only
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture

33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), at separate and distinct session from insertion
33993	Repositioning of percutaneous right or left heart ventricular assist device with imaging guidance at separate and distinct session from insertion
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

HCPCS Coding:

L8698	Miscellaneous component, supply or accessory for use with total artificial heart system
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type
Q0479	Power module for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0480	Driver for use with pneumatic ventricular assist device, replacement only
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only
Q0482	Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only
Q0484	Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0485	Monitor control cable for use with electric ventricular assist device, replacement only
Q0486	Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only
Q0487	Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only
Q0488	Power pack base for use with electric ventricular assist device, replacement only
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only
Q0490	Emergency power source for use with electric ventricular assist device, replacement only
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only
Q0492	Emergency power supply cable for use with electric ventricular assist device, replacement only
Q0493	Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only
Q0494	Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0496	Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0499	Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only
Q0500	Filters for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only
Q0502	Mobility cart for pneumatic ventricular assist device, replacement only
Q0503	Battery for pneumatic ventricular assist device, replacement only, each
Q0504	Power adapter for pneumatic ventricular assist device, replacement only, vehicle type
Q0506	Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only
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

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Ventricular Assist Devices (20.9.1) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Cardiac index: One of many ways to describe the status of the heart's function; relies on cardiac output (CO), and turns cardiac output into a normalized value that accounts for body size. CI uses the following formula: Cardiac Output / Body Surface Area = (Heart Rate * Stroke Volume) / Body Surface Area.

Cardiogenic shock (cardiac shock): A serious condition that occurs when the heart cannot pump enough blood and oxygen to the brain, kidneys, and other vital organs.

Destination therapy: the use of a ventricular assist device (VAD) for long-term, permanent support in those who are not candidates for transplant.

Humanitarian Device Exemption (HDE): a device that is intended to benefit persons by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 people in the United States per year.

Inotropic support: medications to help the heart pump more effectively.

Intra-aortic balloon pump: a machine that helps the heart pump; a catheter threaded into the aorta is equipped with a tip that helps pump blood out of the heart; does not require open chest surgery for placement.

RELATED GUIDELINES:

Heart Transplant, 02-33000-23

Heart and Lung transplant, 02-33000-24

OTHER:

Available mechanical circulatory support devices (may not be an all inclusive list)

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Ventricular assist devices

Heart Assist® 5 Pediatric VAD FDA approval:

- Temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric individuals
- 5-16 years old
- BSA ≥ 0. 7m2 and < 1. 5m2)
- NYHA class IV end stage heart failure
- Refractory to medical therapy
- Is a listed candidates for cardiac transplantation

HeartMate II® FDA approval:

- As destination therapy with NYHA class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and are not candidates for cardiac transplantation
- Life expectancy of less than 2 years
- Intended for use both inside and outside the hospital, or for transportation of those with ventricular assist devices via ground ambulance, fixed-wing aircraft, or helicopter

HeartMate 3™ Left Ventricular Assist System FDA approval:

- Short-term hemodynamic support (bridge to transplant or bridge to myocardial recovery)
- Short-term or long-term mechanical circulatory support (e.g., bridge to transplant, bridge to myocardial recovery, or destination therapy) in adults and children with advanced refractory left ventricular heart failure

Berlin Heart EXCOR® Pediatric VAD FDA approval:

- For bridge to transplant for pediatric individuals
- Severe isolated left ventricular or biventricular dysfunction
- Candidate for cardiac transplant
- Requires circulatory support

HeartWare® Ventricular Assist System FDA approval:

- For hemodynamic support in advanced, refractory left ventricular heart failure, as a bridge to cardiac transplantation (BTT)
- For bridge to myocardial recovery
- As destination therapy (DT) in individuals for whom subsequent transplantation is not planned

Percutaneous ventricular assist devices

Impella® 2.5, Impella® 5.0, Impella® 5.5 with SmartAssist, Impella CP®, and Impella CP with SmartAssist® FDA approval:

- As temporary ventricular support intended for short term use (≤4 days for the Impella 2.5 and Impella CP, and ≤6 days for the Impella 5.0 and Impella LD) for treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open heart surgery, or
- In the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis
- Cardiogenic shock is a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (these may include volume loading and use of pressors and inotropes, with or without IABP)
- Impella® CP is indicated for use during high risk percutaneous coronary interventions

Impella® RP system FDA approval:

- Temporary right ventricular support for up to 14 days for individuals with a body surface area ≥ 1.5m^2 for the following indications:
- Acute right heart failure or decompensation following left ventricular assist device implantation
- Myocardial infarction
- Heart transplant
- Open-heart surgery

TandemHeart® FDA approval:

- Temporary left ventricular bypass of ≤6 hours

Total artificial hearts

SynCardia Temporary Total Artificial Heart (with Freedom® Driver System) FDA approval:

- For use inside the hospital as a bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

AbioCor® Implantable Replacement Heart System FDA approval (via HDE process):

- Severe biventricular end stage heart disease individuals who are not cardiac transplant candidates
- Are younger than 75 years of age
- Require multiple inotropic support
- Are not treatable by left ventricular assist device (LVAD) destination therapy
- Are not weanable from biventricular support if on such support

Right ventricular assist devices

Centrimag® Right Ventricular Assist Device FDA approval (via HDE process):

- Temporary circulatory support for up to 14 days for individuals in cardiogenic shock due to acute right ventricular failure

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/25/24.

GUIDELINE UPDATE INFORMATION:

01/01/01	Medical Coverage Guideline developed.
01/01/02	Annual HCPCS coding update.
09/15/03	Reviewed; revised to delete investigational statement regarding VADs used for destination therapy and add coverage criteria for this indication; added new HCPCS codes for VADs; added clarification for VADs vs. artificial heart devices.
08/15/04	Scheduled review; revised title to include total artificial hearts; added procedure codes for artificial hearts.
05/15/05	Revision to add clarification regarding artificial heart or mechanical devices.
08/15/05	Scheduled review; no change in coverage statement.
08/15/06	Scheduled review (consensus review); no change in coverage statement.
07/15/07	Scheduled review; revised Description section; reformatted guideline; updated references.
07/15/08	Scheduled review; no change to position statement. Add CMS language for clinical trials. Update references. Update Internet links.
01/01/09	Annual HCPCS coding update: update descriptor 0048T; delete 0049T.
07/15/09	Scheduled review; no change in position statement. Update references.
01/01/10	Annual HCPCS coding update: add CPT codes 93750, 33981, 33982, & 33983 and HCPCS code Q0506; remove code range Q0480 – Q0505 and add codes with full descriptors for all replacement parts and accessories.
10/15/10	Revision; related ICD-10 codes added.

01/01/11	Annual HCPCS coding update. Added codes Q0478, Q0479. Revised descriptor for code Q0499.
10/15/11	Unscheduled review. Revised description section, position statement, CPT coding, ICD10 coding and definitions. Deleted Medicare Exception and updated references.
01/01/13	Annual CPT/HCPCS coding update. Added 33990, 33991, 33992 and 33993. Revised descriptor for 93750. Deleted 0048T and 0050T. Corrected descriptors for Q0478 and Q0479.
04/01/13	2nd quarter HCPCS coding update. Added Q0507, Q0508 and Q0509. Deleted Q0505.
06/15/13	Unscheduled review. Revised description section, position statement and program exceptions section. Updated references and reformatted guideline.
07/01/14	Deleted codes 92970 , 92971, 93750, Q0478, Q0479, Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0506, Q0507, Q0508 and Q0509.
11/01/15	Revision: ICD-9 Codes deleted.
03/15/16	Scheduled review. Revised description section and index terms. Maintained position statement. Updated references. Reformatted guideline.
01/01/17	Annual CPT/HCPCS update. Added 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, 0462T, 0463T.
03/15/17	Scheduled review. Revised description section, coverage for rVAD, index terms, and program exceptions section. Updated references. Reformatted guideline.
08/15/17	Revision: updated description section. Added additional coverage indications for percutaneous VAD. Added HCPCS codes Q0478, Q0479, Q0480, Q0481, Q0482, Q0483, Q0484, Q0485, Q0486, Q0487, Q0488, Q0489, Q0490, Q0491, Q0492, Q0493, Q0494, Q0495, Q0496, Q0497, Q0498, Q0499, Q0500, Q0501, Q0502, Q0503, Q0504, Q0506, Q0507, Q0508 and Q0509. Revised index terms. Updated references.
12/15/17	Revision: added the HeartMate III® device and its FDA approved indications to the list of available mechanical circulatory support devices. Updated references.
01/01/18	Annual CPT/HCPCS coding update: added 33927, 33928, 33929, Q0477; deleted 0051T, 0052T, 0053T.
08/15/18	Revision: updated FDA approved indications and references.
01/01/19	Annual CPT/HCPCS coding update. Added L8698.
05/16/19	Revision: updated FDA approval indications for HeartMate III Left Ventricular Assist System and references.
08/15/20	Scheduled review. Revised description. Maintained position statement and updated references.
01/01/21	Annual CPT/HCPCS coding update. Revised 33990, 33991, 33992, 33993; added 33995, 33997.
11/15/21	Revision. Updated FDA approved indications for the HeartMate 3™ Left Ventricular Assist System. Updated references.
01/01/22	Annual CPT/HCPCS coding update. Deleted 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, 0462T, 0463T.

02/15/22	Scheduled review. Revised criteria for implantable VAD/destination therapy and definitions. Updated references.
05/25/23	Update to Program Exceptions section.
02/15/24	Scheduled review. Revised description, revised and reformatted Other section, maintained position statement, and updated references.