2020 CARDIAC RHYTHM & HEART FAILURE HOSPITAL AND PHYSICIAN REIMBURSEMENT GUIDE FOR MECHANICAL CIRCULATORY SUPPORT DEVICES

Medtronic

CONTENTS

This booklet includes the commonly billed hospital and physician codes for Mechanical Circulatory Support Therapy devices and procedures. This is not a comprehensive list of all available codes, and it is possible that there is a more appropriate code for any given procedure.

Disclaimer

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U.S. REIMBURSEMENT GUIDE
OVERVIEW

This guide has been developed to help you understand Medicare and commercial payer coverage and payment for Mechanical Circulatory Support (MCS) therapies. This guide also includes an overview of hospitals' program requirements for implanting MCS devices, specifically ventricular assist devices (VADs).

The HeartWare™ HVAD™ System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

For Medtronic Cardiac Rhythm Heart Failure (CRHF) Reimbursement support, please contact us at 866-877-4102 or via email at rs.healthcareeconomics@medtronic.com.

To access CRHF Reimbursement tools, guides, and/or C-code Finder (allows you to find C-codes by product name or model number), visit our website at: www.medtronic.com/crhfreimbursement. C-code Finder: www.medtronic.com/crhfcodes.

HEARTWARE HVAD
DEVICE DESCRIPTIONS

The HeartWare™ HVAD™ System features a small, implantable, centrifugal blood pump (HeartWare™ HVAD™ Pump) designed to help treat patients suffering from advanced heart failure. The HVAD Pump draws blood from the left ventricle and propels it through an outflow graft connected to the patient's ascending aorta.

The HVAD Pump is supported by surgical implant tools and peripheral equipment, including a monitor, controller, rechargeable battery packs, AC/DC power adapters, battery charger, and patient packs (carrying cases).

HeartWare HVAD Pump

The HVAD Pump, a centrifugal, rotary blood pump, has a displaced volume of 50 cc, a priming volume of 15 cc, an external diameter of approximately 5 cm, and weight of 160 grams. The pump is designed to be implanted in the pericardial space with left ventricular apex to ascending aortic cannulation for left ventricular support. The inflow conduit is integrated with the pump and a 10 mm diameter gel impregnated outflow graft with a strain relief is attached to the pump. Blood flows from the left ventricle into the inflow conduit, where the continuously rotating impeller forces blood out of the outlet housing into the aorta. The pump has one moving part — an impeller — that has integrated motor magnets and utilizes a passive, non-contacting suspension system. The hermetically sealed electric motors within both the front and rear housing generate power to move the impeller. The driveline connects the pump through the abdominal wall to an externally worn controller.

HVAD™ Controller

The HVAD Controller is a microprocessor that controls HeartWare HVAD System operation and management. It sends power and operating signals to the pump and collects and stores information it receives from the pump.

The controller must be connected to two power sources (e.g., electrical outlet and a battery or two batteries) at all times. It has both visible and audible alarm indicators and displays pump flow, speed, and power. The controller has one operating mode, the "Fixed Mode," which maintains a constant motor speed. Using the monitor (see next section), the clinician sets the pump motor speed between 1,800 and 4,000 rpm.

HeartWare Monitor

The HeartWare Monitor is a touch screen computer that uses proprietary software to display system performance information and to permit adjustment of selected controller parameters via a password controlled by the clinical staff. The monitor receives continuous pump information from the controller and displays and stores it in real time. .

The monitor automatically and continually monitors for certain fault or alarm conditions. Alarm conditions are displayed on both the monitor and the controller. The monitor is used only in a clinical setting by a healthcare provider.

POWER SOURCES

HeartWare Battery

The HeartWare battery is rechargeable and provides power to the controller and the implanted pump. Electronics in the battery provide safety and charge status monitoring. The user interface consists of a gas gauge with a four LED bar graph to indicate remaining capacity, and a push button for testing remaining battery capacity.

HeartWare Battery Charger

The HeartWare battery charger has the capacity to simultaneously recharge up to four batteries. Safety features in the battery charger and batteries protect against overcharge, overcurrent, and undervoltage conditions.

HVAD Controller AC/DC Adapters

The HVAD controller AC/DC adapters provide power connection to the controller when the patient is stationary or in a car. In the event of a power loss (e.g., due to thunderstorm), the DC adapter also serves as an emergency backup, allowing patients to get to a location with electrical outlet power.

ACCESSORIES

HeartWare Patient Packs

The HeartWare patient packs hold and protect the controller and 2 batteries while patients are ambulatory.

OTHER HEARTWARE SYSTEM COMPONENTS

Alarm Adapter

The HeartWare alarm adapter is a small red adapter that, when inserted into the controller, will silence the "No Power" alarm if power is removed from the controller.

The HeartWare Driveline cover is a small white cover that slides over the driveline at the point where it connects to the controller.

UNDERSTANDING APPROVED INDICATIONS

HEARTWARE HVAD SYSTEM INDICATION FOR USE

The HeartWare HVAD System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.

Anything outside of this label would be considered off-label use of the HVAD System.

To access additional HeartWare HVAD System resources, please visit: https://www.medtronic.com/us-en/healthcare-professionals/products/cardiac-rhythm/ventricular-assist-devices/heartware-hvad-system.html.

INTERMACS[1] REGISTRY INFORMATION

INTERAGENCY REGISTRY FOR MECHANICALLY ASSISTED CIRCULATORY SUPPORT (INTERMACS)

Intermacs is the United States national registry for patients who are receiving durable mechanical circulatory support device (MCSD) therapy to treat advanced heart failure. Intermacs was launched in 2006 as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and clinicians, scientists, and industry representatives. University of Alabama in Birmingham is the Data and Clinical Coordinating Center (DCC) and is responsible for maintaining the database, which currently has 116 U.S. centers actively participating in it. International centers are able to participate in the database as well.

The registry is voluntary for sites/patients to participate in. However, the Joint Commission mandates that all U.S. centers implanting MCSDs for Destination Therapy (DT) requesting certification must participate in a nationally audited registry, which Intermacs is the only one currently.

Intermacs collects clinical data relevant to MCSDs from pre-implant screening to index hospitalization and through follow-up evaluations. Post implant follow-up data is collected at 1 week, 1 month, 3 months, 6 months, and every 6 months thereafter. Major outcomes after implant, e.g., death, explant, rehospitalization, and adverse events, are entered within 30 days of occurrence and also as part of the defined follow-up scheduled intervals.

Intermacs provides contemporary data to demonstrate outcomes, with additional insight into appropriate risk stratification and patient selection. Death, transplant, and explant are the major endpoints recorded. Complex endpoints include the patient's level of function and quality of life. Critical to the evaluation of current MCSD therapy, these indices are becoming increasingly important as patient survival improves and new devices will be compared for outcomes beyond survival.

The number of MCSDs implanted in the U.S. continues to grow, while the supply of donor hearts does not meet the current demand of advanced heart failure. Despite favorable survival and quality of life outcomes, MCSDs have severe and sometimes life-threatening complications which include infections, thrombosis, and stroke. Analysis of the data collected is expected to facilitate improved patient evaluation and management while aiding in better device development. Registry results are also expected to influence future research and facilitate appropriate regulation and reimbursement of MCSD implantations.

THE JOINT COMMISSION[2] (TJC)

The Joint Commission's Disease-Specific Care (DSC) certification program, launched in 2002, is designed to evaluate clinical programs across the continuum of care. Joint Commission-accredited healthcare organizations may seek certification for care and services provided for virtually any chronic disease or condition.

Advanced certification

The Joint Commission offers an advanced-level of certification in 12 clinical or procedural areas. These programs must meet the requirements for DSC Certification plus additional, clinically specific requirements and expectations. The advanced certification programs are:

- Acute Stroke Ready Hospital
- Advanced Comprehensive Stroke Center
- Advanced Palliative Care
- Advanced Total Hip and Knee Replacement
- Chronic Kidney Disease
- Chronic Obstructive Pulmonary Disease
- Heart Failure
- Inpatient Diabetes
- Lung Volume Reduction Surgery*
- Perinatal Care Certification
- Primary Stroke Center
- Ventricular Assist Device*

*These are required by the Centers for Medicare & Medicaid Services (CMS).

On-site review

The on-site review and the intracycle evaluation help the disease-specific care program identify and correct problems and improve the quality of care and services. To become certified, an organization is evaluated during an on-site review conducted by a Joint Commission reviewer, who will assess:

- How clinical outcomes and other performance measures are used to identify opportunities to improve care.
- Whether the organization leaders understand and commit to improving the quality of care for patients in need of the services the program provides.
- How patients and their caregivers are educated and prepared for discharge.

Reviewers also will validate that evidence-based guidelines are incorporated into daily clinical practices. The on-site review will include the use of the tracer methodology — the cornerstone of The Joint Commission's on-site certification process. The objectives of the tracer methodology include:

- Following the experience of care for patients through the program's entire continuum of care.
- Identifying performance issues in one or more steps of the process or in the interfaces between processes.
- Validating compliance with the standards through interviews and observations.

The tracer methodology permits reviewers to "pull the threads" if there is a reason to believe that an issue needs further exploration.

Ongoing certification requirements

Disease-specific programs that successfully demonstrate compliance with The Joint Commission's requirements during the on-site review are awarded certification for a two-year period. At the end of the first year, the organization is required to participate in an Intracycle Monitoring (ICM) conference call to attest to its continued compliance with the standards and to review performance improvement activities. Certified programs are required to regularly submit data to The Joint Commission, and standardized performance measures are currently available for four certification programs — comprehensive stroke centers, perinatal care, primary stroke centers, and advanced certification in heart failure. All other certified programs may use existing relevant performance measures or self-specify measures based on their goals for improvement.

COVERAGE FOR MECHANICAL CIRCULATORY SUPPORT (MCS) THERAPY

National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1)[3]

MEDICARE COVERAGE POLICY

20.9.1 Ventricular Assist Devices, Medicare National Coverage Determination (NCD), Publication Number 100-03.
Effective Date: 10/30/2013

Implementation Date: 9/30/2014

Benefit Category
Inpatient Hospital Services
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General
A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993):
   Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.
2. Bridge-to-transplant (BTT) (effective for services performed on or after January 22, 1996):
   The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:
   - The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.
   - The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed prior to implantation of the VAD.
3. Destination therapy (DT) (effective for services performed on or after October 1, 2003):
   DT is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.

   Patient Selection (effective November 9, 2010):
   - The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:
     – Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days;
     – Have a left ventricular ejection fraction (LVEF) < 25%; and
     – Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria (effective October 30, 2013):

- Facilities currently credentialed by The Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A) of the Social Security Act (the Act):

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision-making and to provide appropriate informed consent. 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.

The team must include at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs as BTT or DT over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

C. Nationally Noncovered Indications

All other indications for the use of VADs not otherwise listed remain noncovered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

COVERAGE WITH NON-MEDICARE PAYERS

Non-Medicare payers typically determine coverage for procedures based on prior authorization and coverage policies. It is recommended that you review the payer's coverage policy to verify that you have met all the criteria for coverage for your particular patient. Not all published policies apply to all patients covered by a particular payer. We recommend you contact the payer to obtain a prior authorization or prior approval. Asking about coverage or attempting to obtain authorization after implant may result in unpaid claims, leaving both the hospital and the physician without compensation.

CODING FOR MCS THERAPY

ICD-10 PROCEDURE CODES[4] & MEDICARE SEVERITY DIAGNOSIS RELATED GROUP (MS-DRG)[5] ASSIGNMENTS FY 2020

ICD-10 Procedure Code	ICD-10 Procedure Code Description	MS-DRG	MS-DRG Description
02HA0QZ	Insertion of implantable heart assist system into heart, open approach	MS-DRG 001	Heart transplant or implant of heart assist system w/MCC*
		MS-DRG 002	Heart transplant or implant of heart assist system w/o MCC*
02WA0QZ	Revision of implantable heart assist system in heart, open approach	MS-DRG 215	Other heart assist system implant
02PA0QZ	Removal of implantable heart assist system from heart, open approach	MS-DRG 268	Aortic and heart assist procedures except pulsation balloon w/MCC*
		MS-DRG 269	Aortic and heart assist procedures except pulsation balloon w/o MCC*

*MCC = major complication or comorbidity.

CY 2020 PHYSICIAN CODING

CPT®[6]	Description
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle
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
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report

INTERROGATION OF VENTRICULAR ASSIST DEVICES CPT CODE 93750

Interrogation Ventricular Assist Device (VAD) In Person

Patients with an implanted VAD require periodic interrogation of the device. In 2010, CPT code 93750 was created to report this interrogation.

- 93750 Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report.

CPT 93750 is not reported with surgical implantation codes (33975, 33976, 33979, 33981-33983).

CPT 93750 is typically reported with an evaluation and management (E&M) visit code (e.g., 99211-99215).

CMS allows a hospital to report Healthcare Common Procedure Coding System (HCPCS) codes; however, individual hospital clinic operations may vary from center to center. Please consult your internal coding and compliance team for further instruction.

CPT 93750 is a diagnostic service and requires in-person assessment and documentation of device parameters, function, and programming (if performed).

- This documentation must be complete, and in a separate procedure note or in a separate paragraph in the daily rounds summary. If the device did not require adjustments, the documentation must support the assessment and potential need.

Medically Unlikely Edits[7]

Medically Unlikely Edits (MUEs): The maximum units of service that a physician or other qualified healthcare professional would report under most circumstances for a single beneficiary on a single date of service.

Physician MUEs: 4

Facility MUEs: 1
Although at the facility level, the MUE is 1, the professional component may be billed up to the maximum MUEs as specified above. Physicians or other qualified healthcare professionals interrogating the VAD at different times of the day and documenting medical necessity in distinct notes can bill separately for the VAD interrogation.

HCPCS CODES FOR HEARTWARE HVAD ACCESSORIES & SUPPLIES[8]

HCPCS Code	Code Description	HeartWare Product	HVAD Catalog #
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only	Controller Kit	1403US
Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only	Battery Charger	1600US
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only	Shower Bag	2000
Q0506	Battery, lithium-ion, for use with electric or electric/pneumatic VAD, replacement only	Lithium-Ion Battery	1650
Q0498	Holster for use with electric or electric/pneumatic VAD, replacement only	Shoulder Pack	2060US
Q0498	Holster for use with electric or electric/pneumatic VAD, replacement only	Waist Pack	2050US
Q0498	Holster for use with electric or electric/pneumatic VAD, replacement only	Convertible Patient Pack	1475
Q0508*	Miscellaneous supply or accessory for use with implanted VAD	Controller AC Adapter	1430US
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type, replacement only	Controller DC Adapter	1440
Q0508*	Miscellaneous supply or accessory for use with implanted VAD	Controller Alarm Adapter	1450

*In order to clarify the descriptor of the previously used miscellaneous VAD accessory and supply code Q0505, the following code was added in December 2012 to the HCPCS Quarterly Update with an effective date of April 1, 2013:

- Q0508: Miscellaneous Supply or Accessory For Use With An Implanted Ventricular Assist Device. Code Q0508 clarifies that the miscellaneous supplies and accessories billed under this code are for use with implanted VADs. Code Q0508 replaces code Q0505 that was discontinued March 31, 2013. Code Q0508 is a generic and non-specific code and has special coverage instructions requiring manual review for payment by the local contractor.

Medtronic does not provide products associated with either Q0508 miscellaneous supply or accessory for use with implanted VAD (driveline stabilization and dressing supplies) or Q0509 miscellaneous support or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A.

Please note that when determined to be medically necessary, driveline stabilization supplies and dressings used with VADs are covered under the prosthetic device benefit as a supply necessary for the effective use of the VAD/prosthetic device. The claims processing jurisdiction for dressings used with VADs is identical to that of other VAD replacement supplies and accessories and does not fall under DME MAC jurisdiction.

FREQUENTLY ASKED QUESTIONS (FAQ)

Does Medicare grant prior authorization for VAD implant and services?

Traditional (fee-for-service) Medicare does not require or grant prior authorization for services. The CMS created a National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). Local MACs administering traditional Medicare must abide by the NCD coverage guidelines. CMS may choose to make changes to the NCD time to time. It is important to visit the CMS website cms.gov directly to keep current with any policy changes or contact your local MAC with questions.

Some Medicare Advantage Plans, administered by commercial payers, may require prior authorizations. These payers may choose to follow the NCD coverage guidelines or offer more coverage based on the patient's specific policy. Commercial payers administering Medicare Advantage Plans cannot offer less coverage than what is specified in the NCD.

Have there been any written changes to Medicare's covered indications for VAD since September 30, 2014?

No, the National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1) has not changed since September 30, 2014. cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ver=1. However, CMS may choose to make changes to the NCD from time to time. It is important to visit the CMS website cms.gov directly to keep current with any policy changes.

What is the difference between MS-DRG 001 and MS-DRG 002 coding for HVAD Pump Implant (ICD-10 code 02HA0QZ)?

Medicare has determined that procedures involving support with destination therapy, durable, implantable VADs are more similar to heart transplantation than support with bridge-to-transplant, external VADs, and ECMO. Because of this, Medicare decided that implantable VADs, like the HVAD System, would be paid the same amount as heart transplants under MS-DRG 001, Heart Transplant or Implant of Heart Assist System with MCC, or MS-DRG 002, Heart Transplant or Implant of Heart Assist System without MCC. Major complications or comorbidities (MCCs) are specific CMS defined codes for diagnoses that if present as secondary diagnoses may lead to significantly increased hospital resource use. MCCs reflect the highest level of severity. Patients who have documented MCCs during their implant hospital admission may code to the higher MS-DRG 001 with a higher reimbursement rate than cases coded to MS-DRG 002.

Does ICD-10-PCS and/or CPT coding differ depending on whether the HVAD System is implanted by the surgeon via a sternotomy or a thoracotomy approach?

No. Coding remains the same.

How does the billing of HVAD System external equipment work with different payers?

MEDICARE

The HVAD System external equipment and supplies (e.g., batteries, battery charger, carry cases/bags, controller, AC/DC adapters) are considered prosthetic devices and are covered by Medicare Part B. The HVAD System equipment has specific HCPCS level II codes assigned to each item. Medicare requires that VAD external accessories and supplies necessary for patient survival are to be sent home with the patient at time of initial implant discharge and placed as line item charges on the inpatient bill under Revenue Code 274; billed to Medicare Part A.

HVAD System replacement supplies and equipment (given after the initial implant and discharge) may be billed to the Medicare Part B program as medically necessary for the patient as well as based on the equipment's minimum expected product lifetimes. It is ultimately the responsibility of the local carrier or intermediary (MAC) to determine whether the replacement supplies and accessories can be covered and to provide instructions, as needed, on how often these items can be replaced. For example, CMS has determined that the reasonable useful lifetime of the lithium ion battery described by HCPCS code Q0506 is 12 months or per medical necessity.

CMS has given clarification regarding modifiers indicating repair or replacement of Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS), such as VAD accessories and supplies. When the item is being furnished as a replacement for the same item which was lost, stolen, or irreparably damaged, modifier RA should be used. Per the VAD replacement policy outlined in CR3931, if the A/B MAC, local carrier, or intermediary determines that the replacement of the lost, stolen, or irreparably damaged item is reasonable and necessary, then payment for replacement of the item can be made at any time, irrespective of the item's reasonable useful lifetime. CMS reminds providers, suppliers, and Medicare intermediaries and carriers that payment under Part B can only be made for replacement of components and accessories that are reasonable and necessary.

Sources:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0424.pdf

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6945.pdf

The Centers for Medicare & Medicaid Services (CMS) has established DMEPOS fee schedules specific for each state with average reimbursement rates for each item. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.

COMMERICAL PAYERS

For commercial/private payers, HVAD System supplies and accessories are often managed under the patient's major medical benefit, and because they are classified as a prosthetic/orthotic, there is usually not a DME coinsurance or payment cap. Some private payers may follow Medicare and require that the initial supplies given to the patient at time of implant be reported on the inpatient hospital claim. However, other private contracts may include a pre-negotiated "carve-out" so that these charges are paid separately outside of the DRG payment for the hospital stay. It is advisable to request prior authorization for these supplies and accessories before the patient is discharged and at any time replacement equipment is to be given to the patient.

Regardless of the payer, it is advisable that the surgical aftercare diagnosis code Z95.811, which identifies the presence of heart assist device in a patient, should be used on all claims for post-placement supplies and equipment.

Will Medicare pay for replacement supplies if the patient had commercial/private insurance when they were implanted but now has traditional Medicare A/B?

HCPCS level II code Q0509 is a code that covers "miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A." This code is used to report replacement of accessories and supplies for VADs that were not originally paid for by Medicare (e.g., other insurance paid for the implant and hospital stay or the patient was not Medicare-eligible at the time of the surgery), but are now eligible for coverage of the replacement supplies and accessories under Medicare Part B. Coverage for these items that are billed to Medicare Part B are subject to the local Medicare contractor discretion and will be manually reviewed. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7888.pdf.

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[6] CPT® codes and descriptions only are copyright ©2019 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained or not contained herein.
[7] Medically Unlikely Edits. Cms.gov. Available at: https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE. Accessed April 16, 2020.
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Brief Statement

HeartWare™ HVAD™ System
Indications for Use

The HeartWare™ HVAD™ System is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a Bridge to Cardiac Transplantation (BTT), myocardial recovery, or as Destination Therapy (DT) in patients for whom subsequent transplantation is not planned.

Contraindications
The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings and Precautions
Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Serious and life-threatening adverse events, including stroke, have been associated with use of this device. Blood pressure management may reduce the risk of stroke. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not disconnect the driveline from the controller or the pump will stop. Avoid devices and conditions that may induce strong static discharges as this may cause the VAD to perform improperly or stop. Magnetic resonance imaging (MRI) could cause harm to the patient or could cause the pump to stop. The HVAD™ Pump may cause interference with automatic implantable cardioverter-defibrillators (AICDs), which may lead to inappropriate shocks, arrhythmia, and death. Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta — use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD Pump post-CPR.

Potential Complications
Implantation of a VAD is an invasive procedure requiring general anesthesia and entry into the thoracic cavity. There are numerous known risks associated with this surgical procedure and the therapy including, but not limited to, death, stroke, neurological dysfunction, device malfunction, peripheral and device-related thromboembolic events, bleeding, right ventricular failure, infection, hemolysis, and sepsis.

Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events prior to using this device.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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