This booklet includes the commonly billed hospital and physician codes for cardiac rhythm and heart failure 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.

These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.
US 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).

These coding suggestions and coverage guidelines do not replace seeking coding advice from the payer and your institution’s coding and compliance staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

Where reimbursement is requested for the use of a product that may be inconsistent or not expressly specified in the FDA cleared or approved labeling (e.g., instructions for use, operator’s manual, or package insert), consult with your billing advisors or payers for advice on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related services.

Medtronic is focused on providing mechanical circulatory support technology to cardiologists and cardiac surgeons for treating patients in end stage heart failure. The HeartWare™ HVAD™ Ventricular Assist System is FDA approved for Bridge to Transplant (BTT) and as Destination Therapy (DT).

If you have questions after reviewing this guide, please contact the Medtronic Reimbursement and Health Policy team by sending an email to: Rs.healthcareeconomics@medtronic.com
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 (Fig. 1), 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 (Fig. 2) 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 (Fig. 3) is a touchscreen 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 (Fig. 4A) 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 (Fig. 4B) has the capacity to simultaneously recharge up to four batteries. Safety features in the battery charger and batteries protect against over-charge, overcurrent and under-voltage conditions.

HVAD Controller AC/DC Adapters
The HVAD Controller AC and DC Adapters (Figs. 5A and 5B) 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 back up, allowing patients to get to a location with electrical outlet power.
ACCESSORIES

HeartWare Patient Packs
The HeartWare Patient Packs (Fig. 6A) hold and protect the controller and 2 batteries while patients are ambulatory (Fig. 6B).

OTHER HEARTWARE SYSTEM COMPONENTS

Alarm Adapter
The HeartWare Alarm Adapter (Fig. 7A) 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 (Fig. 7B) 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.

Examples of the HVAD System off-label use are:

- Pediatrics
- Right Ventricular Assist Device (RVAD)
- Bi-Ventricular Assist Device (BiVAD)

Disclaimer:
Where reimbursement is requested for the use of a product that may be inconsistent or not expressly specified in the FDA cleared or approved labeling (e.g., instructions for use, operator’s manual, or package insert), consult with your billing advisors or payers for advice on handling such billing issues. This most likely includes the Hospital policy and procedures for off label usage. Some payers may have policies that make it inappropriate to submit claims for such items or related services.
INTERMACS 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.

Source: http://www.uab.edu/medicine/intermacs/about-us
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.

Source: https://www.jointcommission.org

THE JOINT COMMISSION (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 health care 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 twelve 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)

The Joint Commission
COVERAGE FOR
MECHANICAL CIRCULATORY
SUPPORT (MCS) THERAPY

View CMS National Coverage Determination for VAD

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; and,
     • 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 Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, 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.

NON-MEDICARE PAYERS

Non-Medicare payers typically determine coverage for procedures based on prior authorization. It is recommended that you review the payer’s coverage policy and seek prior authorization when required. Asking about coverage after an implant may result in unpaid claims, leaving both the hospital and the physician without compensation.
## CODING FOR MCS THERAPY

### ICD-10 PROCEDURE CODES & MEDICARE SEVERITY DIAGNOSIS RELATED GROUP (MS-DRG) ASSIGNMENTS FY 2018

<table>
<thead>
<tr>
<th>ICD-10 Procedure Code</th>
<th>ICD-10 Procedure Code Description</th>
<th>MS-DRG</th>
<th>MS-DRG Description</th>
<th>Medicare Geometric Mean Length of Stay (LOS)</th>
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</thead>
<tbody>
<tr>
<td>02HA0QZ</td>
<td>Insertion of implantable heart assist system into heart, open approach</td>
<td>MS-DRG 001</td>
<td>Heart transplant or implant of heart assist system w/MCC*</td>
<td>29.0</td>
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<tr>
<td></td>
<td></td>
<td>MS-DRG 002</td>
<td>Heart transplant or implant of heart assist system w/o MCC*</td>
<td>16.8</td>
</tr>
<tr>
<td>02WA0QZ</td>
<td>Revision of implantable heart assist system in heart, open approach</td>
<td>MS-DRG 215</td>
<td>Other heart assist system implant</td>
<td>7.2</td>
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<tr>
<td>02PA0QZ</td>
<td>Removal of implantable heart assist system from heart, open approach</td>
<td>MS-DRG 268</td>
<td>Aortic and heart assist procedures except pulsation balloon w/MCC*</td>
<td>6.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MS-DRG 269</td>
<td>Aortic and heart assist procedures except pulsation balloon w/o MCC*</td>
<td>1.8</td>
</tr>
</tbody>
</table>

SOURCE: CMS FY 2018 IPPS Final Rule and Correction Notice Tables
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page.html

*MCC = Major Complication or Comorbidity
Physician documentation should include specific information about the patient’s disease state to ensure that the acuity of the patient is recognized. All primary and secondary diagnoses must be clearly identified in the patient’s record to facilitate appropriate payment. A MCC is usually a co-morbid condition or complication and not an exacerbation of the primary diagnosis. The FY 2017 Appendix H link titled Diagnoses Defined as Major Complications or Comorbidities is available at:
### CY 2018 PHYSICIAN CODING

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33979</td>
<td>Insertion of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33980</td>
<td>Removal of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td>33982</td>
<td>Replace VAD Pump, Intracorporeal without Bypass</td>
</tr>
<tr>
<td>33983</td>
<td>Replace VAD Pump, Intracorporeal with Bypass</td>
</tr>
<tr>
<td>93750</td>
<td>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</td>
</tr>
</tbody>
</table>
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, a 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, 33981-3398).

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

CMS allows a hospital to report HCPCS (Healthcare Common Procedure Coding System) 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
Medical Unlikely Edits (MUEs): The maximum units of service that a physician or other qualified health care professional would report under most circumstances for a single beneficiary on a single date of service.

Non-Facility 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 health care professionals interrogating the VAD at different times of the day and documenting medical necessity in distinct notes, can bill separately for the VAD interrogation.

Source:
https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html
## HCPCS Codes for Heartware HVAD Accessories & Supplies

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Code Description</th>
<th>HeartWare Product</th>
<th>Catalog #</th>
<th>Photo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0481</td>
<td>Microprocessor control unit for use with electric ventricular assist device, replacement only</td>
<td>Controller Kit</td>
<td>1403US</td>
<td><img src="http://example.com/image1.png" alt="" /></td>
</tr>
<tr>
<td>Q0495</td>
<td>Battery/power pack charger for use with electric/pneumatic VAD, replacement only</td>
<td>Battery Charger</td>
<td>1600US</td>
<td><img src="http://example.com/image2.png" alt="" /></td>
</tr>
<tr>
<td>Q0501</td>
<td>Shower cover for use with electric/pneumatic VAD, replacement only</td>
<td>Shower Bag</td>
<td>2000</td>
<td><img src="http://example.com/image3.png" alt="" /></td>
</tr>
<tr>
<td>Q0506</td>
<td>Battery, lithium-ion, for use with electric or electric/pneumatic VAD, replacement only</td>
<td>Lithium-Ion Battery</td>
<td>1650</td>
<td><img src="http://example.com/image4.png" alt="" /></td>
</tr>
<tr>
<td>Q0498</td>
<td>Holster for use with electric or electric/pneumatic VAD, replacement only</td>
<td>Shoulder Pack</td>
<td>2060US</td>
<td><img src="http://example.com/image5.png" alt="" /></td>
</tr>
<tr>
<td>Q0498</td>
<td>Holster for use with electric or electric/pneumatic VAD, replacement only</td>
<td>Waist Pack</td>
<td>2050US</td>
<td><img src="http://example.com/image6.png" alt="" /></td>
</tr>
<tr>
<td>Q0498</td>
<td>Holster for use with electric or electric/pneumatic VAD, replacement only</td>
<td>Convertible Patient Pack</td>
<td>1475</td>
<td><img src="http://example.com/image7.png" alt="" /></td>
</tr>
<tr>
<td>Q0508*</td>
<td>Miscellaneous supply or accessory for use with implanted VAD</td>
<td>Controller AC Adapter</td>
<td>1430US</td>
<td><img src="http://example.com/image8.png" alt="" /></td>
</tr>
<tr>
<td>Q0478</td>
<td>Power adapter for use with electric or electric/pneumatic VAD, vehicle type, replacement only</td>
<td>Controller DC Adapter</td>
<td>1440</td>
<td><img src="http://example.com/image9.png" alt="" /></td>
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<tr>
<td>Q0508*</td>
<td>Miscellaneous supply or accessory for use with implanted VAD</td>
<td>Controller Alarm Adapter</td>
<td>1450</td>
<td><img src="http://example.com/image10.png" alt="" /></td>
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</tbody>
</table>

* In order to clarify the descriptor of the previously used miscellaneous VAD accessory and supply code Q0505, the following code was added 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 the products associated with both Q0508* Miscellaneous supply or accessory for use with implanted VAD (driveline stabilization and dressing supplies) and 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.
COMMON VENTRICULAR ASSIST DEVICE (VAD) TERMINOLOGY

AICD / ICD (Automatic Implantable Cardioverter Defibrillator):
A small implanted device that delivers electrical shocks to the heart to stop fast and potentially deadly heart rhythms. Sometimes done in conjunction with a pacemaker – BiV (Biventricular pacing) or CRT (Cardiac Resynchronization Therapy).

Anticoagulants / Antiplatelets:
Medications referred to as blood thinners, limiting the blood’s ability to form clots. Common examples include Heparin, Coumadin (Warfarin), Aspirin, Dipyridamole (Persantine®, Boehringer Ingelheim), and Clopidogrel (Plavix®, Bristol-Myers Squibb Co.). All VAD patients are usually required to take an anticoagulant and an antiplatelet while they are living with the VAD.

BiVAD (Bi-Ventricular Assist Device):
Two mechanical heart pumps surgically implanted in the left and right ventricles of the heart.

BTD / BTC (Bridge to Decision / Bridge to Candidacy):
An indication for VAD therapy that may be recognized by insurance companies as a patient who may become a candidate for heart transplantation but is currently not a candidate.

BTT (Bridge to Transplantation):
An indication for VAD therapy recognized by the FDA and many insurance companies as a patient who is a candidate for heart transplantation.

DT (Destination Therapy):
An indication for VAD therapy that is recognized by the FDA and many insurance companies as a patient who is not a candidate for heart transplantation and may live with the device for the rest of their life.

ECHO (Echocardiogram):
An ultrasound that takes pictures of the heart to assess the function of the heart muscle, its shape, valves and if there are any blood clots. A transthoracic echocardiogram (TTE) is an echo test that is non-invasive; the ultrasound done on the outside of the body through the chest wall. A transesophageal echocardiogram (TEE) is when the ultrasound test is conducted with a probe in the esophagus to obtain clearer pictures.

ECMO (ExtraCorporeal Membrane Oxygenation):
A treatment that provides circulatory and respiratory support to the patient on the outside of (external to) the body. Consists of a temporary blood pump and an oxygenator.

EF (Ejection Fraction):
A measurement of how much blood the left ventricle of the heart pumps out with each contraction. Normal EF is 55-70%. Commonly documented during an echocardiogram.

EKG / ECG (Electrocardiogram):
Noninvasive test that checks for problems with the electrical activity of the heart.

HeartMate II® (HMII):
Name of an LVAD manufactured by Abbott Laboratories.

HeartMate 3™:
Name of an LVAD manufactured by Abbott Laboratories.

HeartWare™ HVAD™ System:
Name of the LVAD manufactured by Medtronic.
HVAD™ System:
The shortened name for the HeartWare HVAD Ventricular Assist System, which includes the following:

- **AC/DC Adapter** - Power adapter that uses electrical power from the wall outlet or automobile electrical outlet to run the controller and the VAD.
- **Battery Charger**: Charging unit specifically designed to charge the HVAD lithium-ion batteries. Holds up to 4 batteries at once.
- **Controller**: A small computer that operates the VAD and communicates information about how the VAD is working.
- **Driveline / Percutaneous Cable**: The electrical cable attached to the implanted VAD that passes through the skin (exit site) to connect to the controller and power source. Exit site requires sterile dressing changes for the life of the VAD.
- **HVAD Pump**: A small (160 grams) blood pump that is surgically implanted into the patient’s chest and attaches to the failing heart assisting in delivering non-pulsatile blood flow from the native heart to the rest of the body.
- **Lithium-Ion Battery**: Battery specifically designed to connect to the controller and deliver power to the HVAD Pump. The patient must always have either 2 batteries connected or 1 battery and the AC or DC power adapter.
- **Patient Pack / Waist Pack / Shoulder Pack**: Carrying cases specifically designed to hold the HVAD controller and batteries against the patient’s body.

**Inotrope, Intravenous (IV):**
IV heart failure medications such as milrinone, dobutamine, and dopamine which patients may be given to help the contractility of their heart.

**Intermacs (Interagency Registry for Mechanical Assisted Circulatory Support):**
A national registry of patients with durable Ventricular Assist Devices (VADs) and Total Artificial Hearts (TAHs). Implanting centers are required to participate in a national registry in order to be a Joint Commission Destination Therapy Certified Program.

**LVAD (Left Ventricular Assist Device):**
A mechanical heart pump that is surgically implanted in the left ventricle of the heart. Assists the heart to pump blood to the aorta and the rest of the body. Sometimes referred to as LVAS (Left Ventricular Assist System).

**MCS (Mechanical Circulatory Support):**
A common term referring to patients who have mechanical pumps assisting their failing heart.

**NYHA (New York Heart Association) Classification:**
Categorizes the extent of a patient’s heart failure, Classes 1-4, based on the patient’s physical activity limitations and shortness of breath. VAD Therapy is indicated for severe class 3 and class 4 heart failure.

**OPO (Organ Procurement Organization):**
A non-profit organization in the U.S. that is responsible for the evaluation and obtaining of deceased donor organs for organ transplantation.

**Pacemaker:**
A small implanted device that sends electrical signals to the heart via electrodes to cause the heart to contract. This device is intended to help the body maintain a regular heartbeat.

**PFTs (Pulmonary Function Tests):**
Noninvasive diagnostic tests that provide measurable feedback about the function of the lungs. These tests may be done to determine the lung function of a heart failure patient during the work-up for transplant or VAD.

**RVAD (Right Ventricular Assist Device):**
A mechanical heart pump that is surgically implanted in the right ventricle of the heart. Assists the heart to pump blood to the lungs.

**Six-Minute Walk Test:**
Measures how far a patient can walk in 6 minutes as a sub-maximal test of aerobic capacity / endurance.
Sternotomy:
Surgical incision through the sternum.

TAH:
Total Artificial Heart is a device surgically implanted that replaces the left and right ventricles of the heart, most commonly used in patients suffering from bi-ventricular heart failure.

Thoracotomy:
Surgical incision of the left lateral chest wall.

UNOS (United Network for Organ Sharing):
Established in 1984, a non-profit, scientific, and educational organization that administers the only Organ Procurement and Transplantation Network (OPTN) in the United States under contract with the federal government.

- Heart Transplant Listing Status
  - 1A – The “top of the list” patients waiting for a heart transplant in that region. Patient is usually in the ICU or may have a VAD.
  - 1B – Patients with end-stage heart failure on a VAD or continuous IV Inotrope infusion. May be at home waiting.
  - 2 – Patients who do not meet the criteria to be 1A or 1B but still have end-stage heart failure taking oral heart failure medications. May be at home waiting.
  - Inactive – Patients who are temporarily inactive on the transplant list who will not get a heart transplant until they are reactivated to status 1A, 1B, or 2. Possible reasons for inactivation may include infection, surgical issues, compliance, financial, or location.

VAD:
A Ventricular Assist Device is a mechanical heart pump that is used to support heart function and blood flow in patients with heart failure. Current VADs on the market are continuous-flow pumps; meaning they deliver continuous blood flow to the patient’s body and the patient may or may not have a pulse.

- Durable VAD: A Ventricular Assist Device or mechanical pump that is surgically implanted inside of the body attached to the heart’s right or left ventricle taking blood from the weak heart and pumping it to the rest of the body. A durable VAD is designed to support the patient for long periods of time (months to years); usually discharged from the hospital.
- Temporary VAD: A Ventricular Assist Device or mechanical pump that is surgically or percutaneously (through the skin – not an open procedure) placed, providing assistance to the body’s circulation either directly from the heart or via the arteries and veins. A temporary VAD is designed to support the patient for shorter periods of time (days to weeks); with the patient usually remaining in the ICU.

VO2 max:
Noninvasive diagnostic test that measures the maximum rate of oxygen consumption during exercise. Testing may be done with patients to determine the severity of heart failure.
COMMON INSURANCE TERMINOLOGY

ACA (Affordable Care Act / Patient Protection and Affordable Care Act):
Comprehensive health reform legislation passed in March 2010 consisting of multiple provisions including, but not limited to, expansion of Medicaid eligibility, establishment of health insurance exchanges, and prohibiting insurers from denying coverage due to pre-existing conditions.

ACO (Accountable Care Organizations):
Groups of doctors, hospitals, and other health care providers, who come together to share accountability for the quality, cost and overall care for an assigned population of patients. Each patient’s care is coordinated by a primary care physician. Incentives are created for providers to be more efficient and keep costs down with focus on prevention and quality benchmarks. Typically associated with Medicare and Medicaid plans.

APC (Ambulatory Payment Classification):
Medicare clusters outpatient hospital procedures into groups called APCs based on comparable resource use and clinical similarities. Payment amounts are prospectively assigned to each APC, and those amounts often include all services and supplies used during that episode of care.

Appeal:
Filed by a provider or patient when there has been a denial of coverage, inadequate payment or disagreements with coding.

Benefits:
A general term referring to any service or supply covered by a health insurance plan.

- **COB (Coordination of Benefits)** – Process by which the health insurance company determines if it is the primary or secondary payer for patients who have coverage from more than one insurance policy.

- **EOB (Explanation of Benefits)** – A statement sent from the health insurance company to a member listing the services that were billed by the health care provider, how they were processed, and what amount remaining is the patient’s responsibility.

- **In-network / Out-of-network** – Healthcare rendered to a patient by providers who are considered “preferred providers” by a health insurance company is in-network. Care received by providers outside a health insurance company’s network is out-of-network.

Case Management / Gatekeeper:
Can be designated as another control mechanism, particularly in high risk or high claim disease areas. OPTUM®, an operating company of United Healthcare, is an example of a case management company.

Clinical Trial Coverage Policy:
A payer’s policy that defines how they will or will not cover patients who are enrolled in a clinical trial – which is any research study that prospectively assigns human participants to health-related interventions being studied for the effects on health outcomes.

CMS (Centers for Medicare & Medicaid Services):
A federal agency within the Department of Health and Human Services (HHS) that administers the Medicare and Medicaid programs.

Co-pay:
Specific charge the health insurance company may require patients to pay for specific medical services or supplies.

Coding:
Language that characterizes services and procedures abstracted from sources within the patient’s medical record and submitted to insurance companies as claims for payment.

Coinsurance:
Amount patient must pay for medical services after satisfying co-payment or deductible typically expressed as a % of charges.
Common Insurance Terminology, cont’d.

Commercial Payers:
Any type of health benefit insurance plan not obtained through government funded plans such as Medicare and Medicaid. Examples include for-profit companies like Cigna, Aetna, Humana, United Healthcare, Anthem, and regional companies like most Blue Cross Blue Shield plans.

Compassionate Use:
Request by a provider to a commercial payer when an off label procedure of a device, which is not legally marketed, is being considered (process is usually managed by the medical policy). Medicare does not consider requests for compassionate use. FDA does not require compassionate use submissions for legally marketed devices.

Coverage:
Defines under what circumstances a service, procedure or supply is allowed.

CPT (Current Procedural Terminology):
Coding system developed and updated by the American Medical Association to describe physician and other clinician professional services. Most payers also utilize CPT codes to identify services provided by outpatient hospital and ambulatory surgery services.

Deductible:
Amount specified by some health insurance plans that the patient is required to pay out-of-pocket each year before the insurance company will pay the claims.

DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies):
The acronym DMEPOS is commonly used by CMS and other payers in determining coverage and payment for medical supplies.

• Durable Medical Equipment (DME) is equipment that can withstand repeated use, serves a medical purpose, generally not useful to a person in the absence of illness or injury and is appropriate for home use. Many payers, including Medicare, have a distinct DME benefits separate from inpatient services. Coverage for DME is based on if the item is classified as necessary and reasonable. Replacement of DME may have specific requirements and limitations.

• Prosthetic devices replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. VAD accessories and supplies fall under this category. Coverage for prosthetic devices do not fall under DME benefits, but are usually granted at the time the patient undergoes the procedure that makes necessary the use of the device when furnished on a physician's order. Replacement of prosthetic devices are based on the ordering physician determining medical necessity and usually have less restrictive requirements than DME. (each payer may have additional requirements)

For more in depth review of these categories, see the Medicare Benefit Policy Manual sections 110 and 120 at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

Employer-Sponsored Plan:
Group health insurance offered by, or on behalf of, an employer to their employees. Part of the premiums may be paid by the employer.

• Fully-insured health plan: Traditional employer-sponsored plan. Employer pays premium to insurance carrier. Premium rates are fixed for a year based on number of employees enrolled. Employer selects the coverage benefits. Employees pay deductibles and/or copayments as applicable. The insurance company usually carries all the risk for claims.

• Self-funded health plan: Employers, usually larger companies, operate their own health plan instead of purchasing a fully-insured health plan from an insurance carrier. This plan is usually higher risk for the employer in the event that more claims than expected require payment. Employers may use stop-loss or excess-loss insurance to reimburse themselves in the event that claims exceed a predetermined level. Employers may also elect a variation of self-funded plans such as a partially-funded plan with integrated Health Reimbursement Arrangement (HRA) with high deductibles or offer a Healthcare Reimbursement Plan (HRP) to reimbursement employees for individual health insurance premiums instead of offering a group health plan.

Fee-for-service:
A list of predetermined payments for medical services. Medicare Part B reimburses physicians based on a fee schedule. Private payers will often negotiate fee schedules with physicians and hospitals and then make them part of their contract.
HCPCS (Healthcare Common Procedure Coding System): 
Maintained by CMS as uniform coding method to report professional services, procedures and supplies with two levels of codes. Level I codes consist of five-digit CPT codes. Level II codes consist of ambulance services and prosthetic devices/supplies. HCPCS level II codes start with one letter (which identifies the category of the item in question) followed by four numbers.

HMO (Health Maintenance Organization): 
A health insurance product offered by commercial payers, often referred to as a “gate-keeper” style of health plan. Contracts with an exclusive network of providers with pre-negotiated rates and usually involve care coordinated through a primary care provider.

ICD-10 (International Classification of Diseases, 10th revision): 
Code set developed by World Health Organization (WHO) as a standardized system of describing diagnoses and procedures. Includes Clinical Modification (CM) for diagnostic coding and Procedure Coding System (PCS) for inpatient hospital procedure coding. This code set became effective in the United States in October 2015.

IDE (Investigational Device Exemption): 
FDA categorization of devices under clinical trials, Category A and Category B with 6 designations.
- Category A IDE – Experimental/Investigational, absolute risk has not been established, not covered by Medicare.
- Category B IDE – Non-Experimental/Investigational, represent an incremental risk regarding safety and effectiveness. Medicare’s NCD for VAD allows for coverage of category B2 IDE clinical trials.
  - Category B1 – Devices under investigation to establish substantial equivalence.
  - Category B2 – Class III devices whose technological characteristics and indications are comparable to a PMA-approved device.

IHS (Indian Health Services): 
Operating division within the U.S. Department of Health & Human Services responsible for providing medical and public health services to members of federally recognized Native American Tribes and Alaska Natives. IHS is the principal federal health care provider and health advocate for American Indian people.

Joint Commission Disease Specific Care Certification: 
This certification administered by the Joint Commission (TJC) specifically evaluates each center’s ability to meet specific care quality requirements related to VAD placement and care. The certification is required in order to bill Medicare for Destination Therapy patients.

LCD (Local Coverage Determination): 
Enables the local Medicare Administrative Contractor (MAC) to determine regional medical policy.

MAC (Medicare Administrative Contractor): 
Regional commercial payers that administer Medicare services are: Cahaba GBA (Government Benefit Administrators), Cigna Government Services (CGS), First Coast Service Options, National Government Services (NGS), Noridian, Novitas, Palmetto GBA, Wisconsin Physician Services (WPS).

Managed care: 
A system of health care in which patients agree to visit only certain physicians or hospitals, and in which the cost of treatment is monitored by a managing company by contracts and / or preauthorizations. Different types of managed care plans include HMO, PPO, and POS plans.

MCC (Major Complications or Comorbidities): 
Under the MS-DRG payment system, CMS has a defined list of diagnoses that if present as a secondary diagnosis may lead to significantly increased hospital resource use. MCCs reflect the highest level of severity. Determined by accurate documentation in the medical record, a MCC is usually a co-morbid condition or complication secondary to the diagnosis. It can not too closely relate to the primary diagnosis such as an exacerbation of the primary diagnosis. In coding for VAD implantation, the presence of a MCC will change the MS-DRG from 002 to 001; significantly impacting the reimbursement. For the full Medicare-defined list of MCCs, see https://www.cms.gov/ICD10Manual/version34-fullcode-cms/fullcode_cms/P0001.html
Medicaid:
A federal/state matching program offering coverage for specified low income individuals, pregnant women and children. Can be fee-for-service or managed care.

Medical Necessity:
According to Medicare, medical necessity is defined as healthcare services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet the acceptable standards of medicine. Commercial insurers may have additional definitions or requirement for medical necessity. The medical necessity rationale for for a procedure or service is usually documented in the patient’s medical record and may be used prospectively for prior authorization or in an appeal of a denial of coverage.

Medical Policies:
Guidelines established by organizations to provide guidance to providers regarding the appropriate treatment of patients.

Medicare Part A (Hospital Insurance):
According to cms.gov, Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). It also helps cover hospice care and some home health care. It is usually “premium-free” as part of the entitlement program for those 65 years old or older, disabled, or with end-stage renal disease who have paid Medicare taxes during their working life.

Medicare Part B (Medical Insurance):
According to cms.gov, Medicare Part B (Medical Insurance) helps cover medically necessary doctors’ services and outpatient care. It also covers some other medical services that Part A doesn’t cover, such as some of the services of physical and occupational therapists, ambulance services, DME and some home health care. Those covered by Medicare Part A can sign up for Part B, however, Part B requires beneficiaries to pay premiums and deductibles.

Medicare Part C (Medicare Advantage or Replacement Plans):
Voluntary Medicare coverage offered by commercial plans (Cigna, Aetna, Humana, United and others) which includes basic coverage as with Traditional Medicare but may also include optional coverage like Medicare D and cover gaps in coverage from Traditional Medicare.

Medicare Part D:
Medicare’s optional prescription drug coverage. Beneficiaries of Medicare Part A and/or Part B must electively sign up for a Part D plan.

Medicare, Traditional:
Entitlement program started in 1965 covering those who are over 65 years old, eligible for Social Security or Disabled, or have End-Stage Renal Disease. Usually pays for 80% of covered health care costs. Managed by one of 8 Administrative Contractors.

Modifiers:
CPT modifiers help describe a procedure code without changing the definition of the code. They are 2 characters and may be numeric or alphanumeric. CPT modifiers are copyrighted by the American Medical Association (AMA) and have guidelines and rules for their use.

MS-DRG (Medicare-Severity Diagnosis Related Group):
A system of coding to classify inpatient medical cases for payment used under Medicare’s inpatient prospective payment system (IPPS). A payment amount for each MS-DRG is prospectively set each year, and an entire hospital stay is assigned to a specific DRG for one capped payment amount based upon the condition of the patient and the intensity of services that the patient received during their hospital stay. Many private/commercial insurers also follow a DRG-based payment methodology for inpatient hospital stays.

NCD (National Coverage Determination):
Medicare policy that describes the criteria to be followed on a national basis. A decision made by CMS regarding whether and under what circumstances a specific medical procedure will be covered by the Medicare program. Medicare Administrative Contractors (MACs) must abide by these NCDs, but are often given flexibility as to how the coverage is administered.
Outpatient Prospective Payment System (OPPS):
A payment system used almost exclusively by the Medicare program to reimburse outpatient hospital procedure(s)
based on prospectively set payment amounts called ambulatory payment classifications (APCs) or comprehensive
ambulatory payment classifications (C-APCs).

Payment:
Actual value of a service or procedure. Influenced by hospital–payer contracts.

Peer-to-Peer:
Communication between a provider and commercial insurer, typically physician to physician. Usually occurs
to clarify a specific patient situation which might present a unique clinical circumstance to warrant individual
consideration of coverage based on the review of the patient’s medical record.

PMA:
Any premarket approval application for a class III medical device, including all information submitted with or
incorporated by reference. “PMA” includes a new drug application for a device under section 520(l) of the
FD&C Act.

POS / PPO (Point of Service and Preferred Provider Organization):
Two types of commercial insurance products, most predominant because of the opportunity for large networks
and choice.

Prior Authorization, Pre-certification, Pre-Approval:
Mechanisms used by commercial payers to manage costs and appropriate care in a prospective manner. Medicare,
traditional does not grant prior authorizations.

Reimbursement:
Comprised of three components: Coding, Coverage, Payment

Supplemental Policy:
A health insurance policy sold by private / commercial payers to help pay some of the health care costs such as
copayments, coinsurance and deductibles that may not be paid by the primary insurance plan. Most commonly
found as Medicare Supplement Plans.

TPA (Third Party Administrator):
An organization that processes insurance claims or certain aspects of an employee benefit plan for a separate
entity.

Sources:
http://www.cms.gov
http://www.medicare.gov
http://www.ahacentraloffice.org
http://www.healthcare.gov
http://www.cdc.gov
http://www.khn.org
FREQUENTLY ASKED QUESTIONS (FAQS)

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 Centers for Medicare & Medicaid Services (CMS) created a National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). Local Medicare Administrative Contractors (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 www.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 9/30/2014. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ver=1. However, CMS may choose to make changes to the NCD time to time. It is important to visit the CMS website www.cms.gov directly to keep current with any policy changes.

How do non-Medicare payers determine coverage for MCSD/VAD implants?
Non-Medicare (commercial / private payers) payers may have coverage guidelines or policies for Ventricular Assist Devices, Mechanical Circulatory Support Devices or Artificial Hearts and Related Devices. It is important to contact the payer and request a copy of their guidelines as they are not all the same. Non-Medicare payers typically determine coverage through the prior authorization process. Contact the patient’s payer to determine how you should proceed.

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 (such as: 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 Healthcare Common Procedure Coding System (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:

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?
Healthcare Common Procedure Coding System (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
Which HVAD pieces of external equipment crosswalk to the Q0508 miscellaneous HCPCS code?
Controller AC Adapter and Controller Alarm Adapter.

What are the appropriate Revenue codes for HVAD implant and supplies?
Revenue codes are 3-4 digit numbers used on hospital bills (UB-04 form) that tell the insurance company where the patient was receiving the treatment or what kind of item the patient received as an inpatient. They should be accompanied by a valid procedure code on the bill. For the HVAD Pump implant, revenue code 278, Other Implants is most commonly used.

(Previously revenue code 624, FDA Investigational Devices may have been used for HVAD pump when it was part of a clinical trial).

For all HVAD external equipment, accessories and supplies, revenue code 274, Prosthetic / Orthotic Devices is most commonly used. It is recommended that these codes be reviewed periodically with your hospital’s charge master.

Many centers are following the CMS Transmittal A-03-035 from May 2003, Reporting of Revenue Codes Under the OPPS, which gives instruction on utilizing 274 Rev code. As the memorandum states, CMS does not dictate to hospitals how to use specific HCPCS with certain Rev Codes, but there are likely many interpretation issues. Centers can also refer to Uniform Billing (UB-04) CMS guidance from November 2006 (CMS Manual System Pub 100-04 Medicare Claims Processing Transmittal 1104, page 78).
## LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BIVAD</td>
<td>Bi-Ventricular Assist Device</td>
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<tr>
<td>BTC</td>
<td>Bridge to Candidy</td>
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<td>BTD</td>
<td>Bridge to Decision</td>
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<td>BTT</td>
<td>Bridge to Cardiac Transplantation</td>
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<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<td>CPT®</td>
<td>Current Procedural Terminology</td>
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<td>DMEPOS</td>
<td>Durable Medical Equipment, Prosthetics, Orthotics, and Supplies</td>
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<td>DT</td>
<td>Destination Therapy</td>
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<tr>
<td>ECHO</td>
<td>Echocardiogram</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>HCPCS</td>
<td>Healthcare Common Procedure Coding System</td>
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<td>HMII®</td>
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<td>HM3®</td>
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<tr>
<td>HVAD®</td>
<td>HeartWare Ventricular Assist Device</td>
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<tr>
<td>ICD-10</td>
<td>International Classification of Diseases, Tenth Revision</td>
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<td>ICU</td>
<td>Intensive Care Unit</td>
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<td>IDE</td>
<td>Investigational Device Exemption</td>
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<td>Interagency Registry for Mechanically Assisted Circulatory Support</td>
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<td>LOS</td>
<td>Length of Stay</td>
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<td>LV</td>
<td>Left Ventricle</td>
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<td>LVAD</td>
<td>Left Ventricular Assist Device</td>
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<td>LVAS</td>
<td>Left Ventricular Assist System</td>
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<td>LVEF</td>
<td>Left Ventricular Ejection Fraction</td>
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<td>Mechanical Circulatory Support</td>
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<td>MCSD</td>
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<td>MS-DRG</td>
<td>Medicare Severity-Diagnosis Related Group</td>
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<td>National Coverage Determination</td>
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<td>New York Heart Association</td>
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<td>PMA</td>
<td>Premarket Approval</td>
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<td>Right Ventricular Assist Device</td>
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<td>TAH</td>
<td>Total Artificial Heart</td>
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<td>UNOS</td>
<td>United Network for Organ Sharing</td>
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<td>VAD</td>
<td>Ventricular Assist Device</td>
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<td>WHO</td>
<td>World Health Organization</td>
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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/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. The IFU can be found at www.heartware.com/clinicians/instructions-use.

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