



Abbott Coverage and Frequently Asked Questions (FAQs) Guide Mechanical Circulatory Support (MCS)

This guide provides coverage and reimbursement information for the implantable HeartMate II™ Left Ventricular Assist Device (LVAD) and HeartMate 3™ LVAD procedures. Abbott offers reimbursement support via email at VADReimbursement@abbott.com. Customer reimbursement assistance is provided subject to the disclaimers set forth in this guide.

TABLE OF CONTENTS

| | |
|---|-----|
| Coverage for Ventricular Assist Devices (VADs)..... | 2 |
| Coverage for VAD Accessories and Supplies Furnished at the Time of Implant | 2 |
| Coverage for Outpatient Replacement VAD Supplies and Accessories | 3 |
| Medicare Coverage for Replacement VAD Supplies and Accessories | 3 |
| Private Insurance Coverage for Replacement VAD Supplies and Accessories | 3 |
| VAD Driveline Dressing Changes and Sterile Supplies..... | 3 |
| Commercial Payer Considerations | 3 |
| FAQs..... | 4 |
| INTERMACS® Registry | 4 |
| NCD for VADs | 4 |
| Coverage for HeartMate 3™ LVAD..... | 4 |
| CMS Certification for VAD Facilities | 4 |
| Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology..... | 4 |
| Common Clinical Scenarios Involving VADS | 5 |
| Global Surgical Periods..... | 6 |
| VAD Interrogation..... | 6 |
| LVAD Accessories and Supplies | 6 |
| VAD Driveline Stabilization Systems/Dressings | 6 |
| LVAD Replacement Accessories and Supplies — Hospital Outpatient or Physician Office Setting | 7–8 |
| References | 8 |

Please note: All FAQs come from frequently asked questions to the HE&R Reimbursement team and from Reimbursement expert experience.

COVERAGE FOR VENTRICULAR ASSIST DEVICES (VADS): NCD 20.9.1 EFFECTIVE DECEMBER 1, 2020

On December 1, 2020, The Centers for Medicare and Medicaid Services (CMS) finalized coverage for patients based on characteristics for VAD candidacy rather than on designations based on intent-to-treat (e.g., bridge-to-transplantation and destination therapy). CMS created a central pathway for qualifying VAD candidacy for coverage and payment that leverages the strong clinical data from the MOMENTUM 3 pivotal trial. They emphasized the NCD is limited to durable, intracorporeal, left ventricular assist devices (LVADs) and does not include temporary VADs or extracorporeal membrane oxygenation (ECMO). In addition, CMS stated that LVADs are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients. The NCD is effective on dates of service on and after December 1, 2020.

Specifically, the coverage criteria for VAD include the following:

- Have New York heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) \leq 25%; and
- Are inotrope dependent; OR have a Cardiac Index (CI) $<$ 2.2 L/min/m², while not on inotropes, and also meet one of the following:
 - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
 - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days

The facility criteria remained the same as it relates to the operator and facility credentialing criteria. More specifically, these include the following:

- Implanting centers are required to have a “heart team” based at the institution, which includes:
 - Cardiac surgeon: At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal LVADs over the course of the previous 36 months with activity in the last year.
 - Cardiologist: 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 placement of a VAD.

- A VAD program coordinator
- A social worker
- A palliative care specialist

For the more information on the NCD 20.9.1 for VADs and the complete analysis of the final decision memo effective on December 1, 2020, please go to <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=298>.

For facilities to provide short-term and long-term mechanical circulatory support for VAD implants, CMS continues to require that facilities be certified by an accrediting body for LVADs. The Joint Commission and DNV GL have developed certification standards for LVAD facilities that would like to obtain coverage to perform implants for Medicare patients.

Most private payers have positive coverage policies for short-term and long-term mechanical circulatory support for LVADs. Providers are encouraged to verify coverage in light of the updated NCD for VADs effective on December 1, 2020. Medicare Advantage Plans are required to follow the updated NCD for VADs.

COVERAGE FOR VAD ACCESSORIES AND SUPPLIES FURNISHED AT THE TIME OF IMPLANT

The VAD device itself should be charged as a line item on the inpatient bill under Revenue Code 278 (Other Implants), which identifies it as an implantable prosthetic device. As with any item, the hospital should set its charge pursuant to hospital protocol and policy. VAD accessories and supplies are necessary for the function of the implanted VAD device itself. The initial VAD supplies and accessories that go home with the patient should be charged as a line item on the inpatient bill under Revenue Code 274 (Prosthetic/Orthotic Devices).²

For Medicare, all of these items are reimbursed as part of the MS-DRG payment for the implant admission. The VAD accessories are not considered Durable Medical Equipment (DME).

For commercial payers, these items should be handled under the major medical benefit and may be paid separately per the hospital’s specific contract with the payer. Because these items are part of the Prosthetics/Orthotics benefit category, they should not be subject to DME co-insurance or payment caps.

Coverage for Outpatient Replacement VAD Supplies and Accessories

MEDICARE COVERAGE FOR REPLACEMENT VAD SUPPLIES AND ACCESSORIES

For Medicare payment, CMS guidance states that medically necessary replacement items can be separately billed and reimbursed when provided in the physician office, in a hospital outpatient clinic or by a third-party supplier able to bill to the local Part B MAC .³ Typically, these items are replaced more than one year from the date of discharge. Documentation of both medical necessity and that the items were provided to the patient is required.

If replacement is medically necessary because the patient lost an item or an item was stolen or irreparably damaged prior to one year from discharge, the modifier “-RA” must be added to the Healthcare Common Procedure Coding System (HCPCS) code and medical necessity must be clearly documented .⁴

HCPCS codes for LVAD accessories and supplies fall under the prosthetic benefit category. A facility does not have to be a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) provider to bill under the prosthetic benefit. The HCPCS codes can be billed to the Part B Medicare contractor when provided in the hospital outpatient setting (under Revenue Code 274), in the physician office setting or by a third- party supplier or other suppliers able to bill their local Part B MAC or private payer.

Payment information specific to replacement VAD supplies and accessories is found on the CMS website under the DMEPOS fee schedule for the most current quarter of the year.

PRIVATE INSURANCE COVERAGE FOR REPLACEMENT VAD SUPPLIES AND ACCESSORIES

As with other items needed for home use, obtaining pre-authorization prior to the patient’s discharge is highly recommended when dealing with private insurers. Private insurers frequently use HCPCS codes to describe these supplies and accessories and allow billing post-discharge for these items, but frequently they opt to reimburse VAD accessories and supplies upon discharge. Commercial payers generally will pay for replacement accessories and supplies at 12 months post- discharge like Medicare, but prior authorization is vital. At the time of prior authorization for the VAD implant, assume every VAD patient will be discharged from the hospital and make arrangements with the payer to ensure your costs for discharge and any post-discharge replacement items will be covered either through an existing carve-out contract or through individual contract negotiation.

Remember to keep your VAD program in mind the next time contract negotiations come around, as that is a prime opportunity to establish agreed protocol for claims submission and reimbursement. Discuss the possibility of

obtaining separate payment for the VAD pump, accessories and supplies billed in Revenue Codes 274 and 278 with the Managed Care Department of your hospital. These separate payments, known as “carve outs,” are often available for implantable prosthetic devices.

VAD DRIVELINE DRESSING CHANGES AND STERILE SUPPLIES

Patients out of the hospital who are supported on a VAD require dressing changes to keep their driveline exit site healthy and patent. This can be compared to an ostomy site. Patients utilize these dressing supplies for home use. Coverage and payment jurisdiction are at the local contractor level. These supplies are not under the coverage and payment jurisdiction of the Durable Medical Equipment Medicare Administrative Contractors (DMEMACs).

- Effective April 1, 2013, driveline stabilization systems/ dressings should be billed using Q0508, miscellaneous VAD accessory or supply on a claim, under Revenue Code 274, with the visit, when performed; provide the amount necessary until the next clinic visit or as needed per your clinical protocol.
 - Physician office visits bill on a CMS 1500 claim form.
 - Hospital outpatient visits bill on a UB04 claim form.
 - Third party suppliers can bill on a CMS 1500 claim form.
- Providers should describe the items provided as “Driveline Stabilization Supplies for Ventricular Assist Device Driveline Care” or “Driveline Stabilization Supplies” and be prepared to submit an invoice, as the claim will be manually reviewed by Medicare and other payers since this is a miscellaneous VAD supply code and payment is carrier priced.
- Effective January 1, 2016, the Medicare hospital outpatient prospective payment system rule approved a separate payment for HCPCS Code Q0508 when provided in the hospital outpatient setting. This code had been incorrectly packaged into the payment for the visit during 2014 and 2015, but CMS changed the status indicator back to being separately paid. However, at the same time they put a Medically Unlikely Edit (MUE) of one on each of these codes, meaning that only one unit per day would be paid. The MUE has been corrected from one unit to 24 units for Q0508 for outpatient hospital providers effective on January 1, 2017.
- Include ICD-10-CM Diagnosis Code Z95 .811 to describe this patient as status post VAD placement.

This code change is explained in this CMS Program Transmittal R1159OTN5 and CMS MLN Matters MM7888 .^{5,6}

COMMERCIAL PAYER CONSIDERATIONS

For hospitals just starting a VAD program, you may have a “new technology” clause in your commercial payer contracts that allows you to negotiate a rate for the VAD implant admission, including the cost of the VAD and all accessories and supplies without opening the entire contract for renegotiation. Check with the hospital managed care department about this possibility.

FAQs

INTERMACS⁺ REGISTRY

What is the INTERMACS Registry?

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) Registry is a North American National Registry for MCS FDA-approved devices that are used to treat advanced heart failure. Most hospitals that provide MCS therapy participate in this national registry to ensure facilitation of long-term data collection efforts for best treating these indicated patients. Initially, participation in INTERMACS Registry was a requirement by CMS for covering formerly destination therapy for Medicare patients. CMS no longer requires participation in INTERMACS Registry as a condition of coverage. But hospitals may still be required to participate in INTERMACS Registry based on the requirements of the organization's certifying agency.

If CMS does not require INTERMACS Registry reporting, do I need to place the national clinical trial (NCT) number on claims to support submission to the local Medicare contractor?

FDA-approved VADs provided to populations indicated in CMS's NCD 20.9.1 do not require an NCT when used in a commercial setting. CMS made this previous update to the NCD effective October 30, 2013, signifying that sufficient evidence has been collected from VADs to remove them from coverage with evidence development (e. g., reporting to the INTERMACS Registry as a condition of coverage).

NCD FOR VADS

What are the key highlights of the final NCD for VADs based on the December 1, 2020, update?

The coverage highlights of the final NCD (20.9.1) for VADs are as follows:

- Coverage for short-term (bridge-to-transplant, bridge-to-recovery) or long-term (destination therapy) mechanical circulatory with FDA-indicated device.
- Coverage based on central criteria for VAD candidacy for Medicare coverage and payment. CMS removed the pre-implant designations (bridge-to-transplant and destination therapy) in favor of one unified patient criteria.
- Removal of the listing requirement for patients on the UNOS Organ Procurement and Transplantation Network (OPTN).
- Removal of the requirement that the implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center prior to implantation of the VAD.

- Facility requirement remains the same as institutions performing VAD implants must have certification from an approved CMS accrediting organization.

Is the HeartMate 3™ LVAD covered under the NCD for VADs?

The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term MCS (e. g., as BTT or myocardial recovery, or DT) in patients with advanced refractory left ventricular heart failure. CMS has indicated that the HeartMate 3 LVAD FDA indication for “short-term” and “long-term” would crosswalk to the former BTT and DT terminology respectively under the NCD 20.9.1 for VADs when appropriate criteria are met.

CMS CERTIFICATION FOR VAD FACILITIES

What certification must hospitals receive to be covered by Medicare for VAD implants?

Hospitals providing VAD implants to Medicare beneficiaries must be certified by an organization approved by CMS. The approved certifying organizations to facilitate this process for CMS are The Joint Commission and DNV GL. Facilities must be certified by either of these organizations to receive Medicare coverage and payment for VAD implants.

PHYSICIAN SPECIALTY CODE CREATED FOR ADVANCED HEART FAILURE AND TRANSPLANT

CARDIOLOGY

Did CMS create a physician specialty code for Advanced HF and Transplant Cardiology?

Yes. CMS established physician specialty code C7 specific to Advanced Heart Failure and Transplant Cardiology effective on October 1, 2017. Impacted physicians will need to update their physician specialty designation on their Medicare enrollment application (CMS 855I or CMS 855O) or via the internet-based Provider Enrollment, Chain and Ownership System. Providers should update their specialty within 60 days of implementation date (October 2, 2017) and make sure their billing team is aware of this change. For additional information, please go to the MLN Matters MM9957 and refer to CR Transmittal R283FM and R3762CP.

COMMON CLINICAL SCENARIOS INVOLVING LVADS

What is the potential coding for common clinical scenarios involving LVAD procedures?

The HeartMate II™ and HeartMate 3™ LVADs utilize the same ICD-10 procedure codes for VAD reporting and map to the same payment MS-DRGs.

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SCENARIO 1 — LVAD IS USED FOR BTT

Procedures - HeartMate II LVAD or HeartMate 3 LVAD (Referred to as HeartMate™ LVAD in Scenario 1 as both LVADs would be applicable)

ICD-10 PCS Codes*

MS-DRG

| SCENARIO | Procedures | ICD-10 PCS Codes* | MS-DRG |
|------------|--|--|---|
| SCENARIO A | <ul style="list-style-type: none"> HeartMate LVAD is implanted HeartMate LVAD is removed Patient is transplanted | 02HA0QZ implant 02PA0QZ removal 02YA0Z0 transplant | 001 or 002 |
| SCENARIO B | <ul style="list-style-type: none"> HeartMate LVAD is implanted Patient is discharged on the VAD Patient returns to hospital for transplant | 02HA0QZ implant Second admit: 02YA0Z0 transplant | 001 or 002 Second admit: 001 or 002 |
| SCENARIO C | <ul style="list-style-type: none"> HeartMate LVAD is implanted Patient is discharged on the VAD Patient returns to the hospital for pump exchange HeartMate LVAD is removed HeartMate LVAD is implanted | 02HA0QZ implant 02PA0QZ removal 02HA0QZ implant | 001 or 002 Second admit: 001 or 002 |

SCENARIO 2 — LVAD IS USED FOR DT

Procedures - HeartMate II LVAD or HeartMate 3 LVAD (Referred to as HeartMate LVAD in Scenario 2 as both LVADs would be applicable)

ICD-10 PCS Codes*

MS-DRG

| Procedures | ICD-10 PCS Codes* | MS-DRG |
|-----------------------------|-------------------|------------|
| HeartMate LVAD is implanted | 02HA0QZ implant | 001 or 002 |

SCENARIO 3 — REMOVAL AND REPLACEMENT OF LVAD

Procedures - HeartMate II LVAD or HeartMate 3 LVAD (Referred to as HeartMate LVAD in Scenario 3 as both LVADs would be applicable)

ICD-10 PCS Codes*

MS-DRG

| Procedures | ICD-10 PCS Codes* | MS-DRG |
|--|--------------------------------------|------------|
| HeartMate LVAD is removed and exchanged with a new HeartMate LVAD device | 02PA0QZ: removal 02HA0QZ: implant | 001 or 002 |

SCENARIO 4 — REVISION OF LVAD

Procedures - HeartMate II LVAD or HeartMate 3 LVAD

ICD-10 PCS Codes*

MS-DRG

| Procedures | ICD-10 PCS Codes* | MS-DRG |
|---|-------------------|--------|
| Correcting a portion of a malfunctioning device or a displaced device | 02WA0QZ | 215 |

*The revision code (02WA0QZ) is not applicable to an exchange because of the definition of

Revision:

Revision—Root Operation W

- Revision is defined as correcting, to the extent possible, a malfunctioning or displaced device. Revision can include correcting a malfunctioning device by taking out and/or putting in part of the device.
- Revision is coded when the objective of the procedure is to correct the positioning or function of a previously placed device, without taking the entire device out and putting a whole new device in its place. A complete re-do of the original root operation is coded to the root operation performed.

GLOBAL SURGICAL PERIODS

Does coding associated with insertion or removal of VADs have a global surgical period?

No. CPT* codes associated with both the insertion of a VAD and explants of a VAD do not have global billing periods, meaning that any follow-up or post-op visits, including VAD interrogation, documented by the physician can be billed and paid separately using the appropriate procedure code, beginning the day after implantation or the day after explant for recovery.

VAD INTERROGATION

Is there coding associated with interrogation of a VAD?

Effective on January 1, 2011, the American Medical Association CPT Editorial Panel created a CPT code specific for interrogation of a VAD device described by CPT Code 93750 (interrogation of ventricular assist device [VAD], in person, with physician analysis of device parameters [e.g., drivelines, alarms, power surges], review of device function [e.g., flow and volume status, septum status, recovery], with programming, if performed, and report).

This code is not reported with any of the surgical implantation codes (33975, 33976, 33979, 33981–33983), but is typically reported in conjunction with an evaluation and management visit code (e.g., 99211–99215) and is reimbursed in addition to the visit code. Documentation in the patient's chart must support both the level chosen for the visit as well as the VAD interrogation code. There are no Correct Coding Initiative edits for the interrogation code. It can be billed once, per day, per patient, per specialty, if medical necessity is adequately documented. Nurse Practitioners (NPs) should check both with their compliance department as well as their state-specific scope of services before independently billing for VAD interrogation.

Who can bill for the VAD interrogation procedure?

The following providers are approved to bill for the VAD interrogation procedure:

- Physicians (cardiologist and surgeons)
The surgeon and cardiologist may both bill on the same day if they perform separate interrogations based on medical necessity.
- NPs or Physician Assistants (PAs) may bill code if:
 - Clinician is approved by the hospital to bill
 - Clinicians should check their state requirements to determine if this falls within scope of services
 - Clinicians have their own provider number
- Nurses may not use code to bill for services:
 - They may download data for physician (or NP/PA) for interpretation and analysis

What should be included when performing a VAD interrogation?

Per CPT the VAD interrogation should include:

- Analysis of the device parameters
- Review of device function and programming, if performed
- A report is included on this service
- This procedure should not be reported on the day of the VAD surgery

Where can VAD interrogations be performed?

The appropriate sites of services where VAD interrogations can be performed are the following:

- Inpatient hospital setting
- Hospital outpatient clinic
- Physician office setting

LVAD ACCESSORIES AND SUPPLIES

How are LVAD accessories and supplies billed with the initial implant performed in the inpatient hospital?

For Medicare beneficiaries, per Program Transmittal 613, inpatient reimbursement for LVAD accessories and supplies is included in the MS-DRG payment to hospitals for the implant admission. Medicare requires that all accessories and supplies necessary for patient survival be placed as line-item charges on the inpatient bill. Therefore, all accessories and supplies needed by LVAD patients during the inpatient stay and post-discharge at home should be included on the inpatient bill.

How are LVAD accessories and supplies billed when furnished outside of the implant procedure?

HCPCS codes for LVAD accessories and supplies fall under the prosthetic benefit category. A facility does not have to be a DMEPOS provider to bill under the prosthetic benefit. The appropriate HCPCS codes can be billed to the Part B Medicare contractor when provided in the hospital outpatient setting (under Revenue Code 274), in the physician office setting or by a third-party supplier (Program Transmittal R1159OTN). Commercial payers may have different requirements; prior authorization is strongly suggested.

VAD DRIVELINE STABILIZATION SYSTEMS/DRESSINGS

What is the appropriate HCPCS code for billing driveline stabilization systems and dressings?

Effective April 1, 2013, CMS created Code Q0508 (miscellaneous VAD accessory or supply for use with any implanted VAD) for reporting driveline stabilization systems (e.g., dressings). There is not a defined DMEPOS payment rate associated with this code and it is reimbursed at the local contractor's discretion with supporting invoice and documentation. Effective on January 1, 2017, CMS has updated the MUE associated with this code from "1" to "24" units for outpatient hospital providers. For physician office providers, the MUE is "4".

LVAD REPLACEMENT ACCESSORIES AND SUPPLIES — HOSPITAL OUTPATIENT OR PHYSICIAN OFFICE SETTING

What are the most common HCPCS codes that support the LVAD replacement accessories and supplies?

| HCPCS ⁷ | CMS Description | CAT # | HeartMate II™ and/or HeartMate 3™ LVAD Replacement |
|--------------------|--|----------|---|
| Q0477 ⁸ | Power module patient cable for use with electric or electric/pneumatic ventricular device, replacement only | 103426 | Power Module Patient Cable |
| Q0478 | Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type | 2230 | Power Module DC Input Cable (car charger) |
| Q0479 | Power module for use with electric/pneumatic ventricular assist device, replacement only | 1340 | Power Module |
| | | 107754 | Mobile Power Unit |
| Q0481 | Microprocessor control unit for use with electric ventricular assist device, replacement only | 106762 | HeartMate II LVAD System Controller |
| | | 106531US | HeartMate 3 LVAD System Controller |
| Q0483 | Monitor/display module for use with electric ventricular assist device, replacement only | 1286 | Display Module |
| Q0485 | Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only | 103871 | Display Module to Power Module Cable |
| Q0495 | Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only | 1440 | Universal Battery Charger |
| Q0496 | Battery for use with electric or electric/pneumatic ventricular assist device, replacement only (excludes Li-Ion) | 109200 | Power Module Backup Power (bill each when performing Planned Maintenance on the Power Module) |
| Q0497 | Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only | 2865 | 14-Volt Battery Clips Set (bill each) |
| Q0498 | Holster for use with electric or electric/pneumatic ventricular assist device, replacement only | 104229 | Holster Vest, 14-Volt Li-Ion, Small |
| | | 104230 | Holster Vest, 14-Volt Li-Ion, Medium |
| | | 104231 | Holster Vest, 14- Volt Li-Ion, Large |
| | | 104217 | GoGear™ Wearables Holster Vest, 12-Volt SLA, Small |
| | | 104218 | GoGear Wearables Holster Vest, 12-Volt SLA, Medium |
| | | 104219 | GoGear Wearables Holster Vest, 12-Volt SLA, Large |
| | | 104224 | GoGear Wearables Holster Vest, 14-Volt Li-Ion, Small |
| | | 104225 | GoGear Wearables Holster Vest, 14-Volt Li-Ion, Medium |
| | | 104226 | GoGear Wearables Holster Vest, 14-Volt Li-Ion, Large |
| | | 104234 | Battery Holster (Pocket Controller) |
| Q0499 | Belt/vest/bag for use with electric or electric/pneumatic ventricular assist device, replacement only | 104220 | GoGear Wearables Modular Belt, 12-Volt SLA, Small/Medium |
| | | 104221 | GoGear Wearables Modular Belt, 12-Volt SLA, Large |
| | | 104227 | GoGear Wearables Modular Belt, 14-Volt Li-Ion, Small/Medium |
| | | 104228 | GoGear Wearables Modular Belt, 14-Volt Li-Ion, Large |
| Q0499 | Belt/vest/bag for use with electric or electric/pneumatic ventricular assist device, replacement only | 106449 | Consolidated Bag, Left (for use with the Pocket Controller) |
| | | 104233 | Consolidated Bag, Right (for use with the Pocket Controller) |
| | | 104222 | Consolidation Bag, Black |

| | | | |
|-------|---|----------|---|
| Q0501 | Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only | 104232 | Shower Bag |
| | | 104216 | GoGear™ Wearables Shower Kit |
| Q0506 | Li-Ion battery for use with electric or electric/pneumatic ventricular assist device, replacement only | 2465 | 14-Volt Li-Ion HeartMate™ Battery (bill each) |
| | | 106128 | 11-Volt Li-Ion Pocket Controller Battery |
| Q0508 | Miscellaneous supply or accessory for use with any implanted ventricular assist device | 103860 | Power Module/AC Cord |
| | | 100759 | Stabilization Belt, Small |
| | | 100760 | Stabilization Belt, Medium/Large |
| | | 1260 | Travel Case (Non-covered by Medicare. Commercial payers may reimburse) |
| | | 106129 | Wearable Accessory Kit |
| | | 106525US | HeartMate 3™ LVAD Modular Cable |
| Q0509 | Miscellaneous supply or accessory for use with any implanted ventricular assist device for which payment was not made under Medicare Part A | | Any LVAD replacement supply or accessory provided for a Medicare patient who was not a Medicare beneficiary at the time of LVAD implant |

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Please note: All FAQs come from frequently asked questions to the HE&R Reimbursement team and from Reimbursement expert experience.

Important Safety Information

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3™ Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

HeartMate II™ LVAS Indications: The HeartMate II™ Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIb or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

HeartMate 3™ and HeartMate II™ LVAS Contraindications: The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3™ and HeartMate II™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System are listed below: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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