ABBOTT CODING GUIDE

MECHANICAL CIRCULATORY SUPPORT (MCS)

LEFT VENTRICULAR ASSIST DEVICE (LVAD), (HEARTMATE II™ OR HEARTMATE 3™ LVADS)

ACUTE MCS (CENTRIMAG™ OR PEDIMAG™ PUMPS)

Effective January 1, 2020

MECHANICAL CIRCULATORY SUPPORT (MCS)

Effective January 1, 2020

Introduction

The Mechanical Circulatory Support (MCS) Coding Guide is intended to provide coding and reimbursement information for providers regarding the implantable HeartMate II™ Left Ventricular Assist Device (LVAD), HeartMate 3™ LVAD and the CentriMag™ acute circulatory support system including the CentriMag™ pump and the PediMag™ pump procedures.

Reimbursement Hotline

In addition, Abbott offers a reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430 or hce@abbott.com. This guide and all supporting documents are available https://www.cardiovascular.abbott/us/en/hcp/reimbursement/heart-failure.html. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

Disclaimer

This document and the information contained herein is for general information purposes only and is not intended and does not constitute legal, reimbursement, coding, business or other advice. Furthermore, it is not intended to increase or maximize payment by any payer. Nothing in this document should be construed as a guarantee by Abbott regarding levels of reimbursement, payment or charge, or that reimbursement or other payment will be received. Similarly, nothing in this document should be viewed as instructions for selecting any particular code. The ultimate responsibility for coding and obtaining payment/reimbursement remains with the customer. This includes the responsibility for accuracy and veracity of all coding and claims submitted to third-party payers. Also note that the information presented herein represents only one of many potential scenarios, based on the assumptions, variables and data presented. In addition, the customer should note that laws, regulations, coverage and coding policies are complex and updated frequently. Therefore, the customer should check with their local carriers or intermediaries often and should consult with legal counsel or a financial, coding or reimbursement specialist for any coding, reimbursement or billing questions or related issues. This information is for reference purposes only. It is not provided or authorized for marketing use.

ABBOTT CODING GUIDE

LEFT VENTRICULAR ASSIST DEVICE (LVAD)

(HEARTMATE II™ OR HEARTMATE 3™ LVADS)

Effective January 1, 2020

CODING AND REIMBURSEMENT FOR LVAD

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
Left Ventricular Assist Device (LVAD) Procedures				
LVAD IMPLANT*				
33979	Insertion of ventricular assist device, implantable, intracorporeal, single ventricle	37.50	$2,039	NA
LVAD REMOVAL				
33980	Removal of ventricular assist device, implantable, intracorporeal, single ventricle	33.50	$1,861	NA
LVAD REPLACEMENT				
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass	37.86	$2,047	NA
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass	44.54	$2,420	NA
LVAD INTERROGATION**				
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	0.92	$50	$59

* Please note that LVAD implant, removal, and replacement procedures are restricted by Medicare to the inpatient hospital site of service.

**Surgeons are able to bill for post implant visits and VAD interrogation starting the day after the VAD implantation, when documented appropriately, as there is a zero-day global period. Please consult your professional coding staff for documentation guidelines. 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 (CCI) edits for the interrogation code. It can be billed once, per day, per patient, per specialty, if medical necessity is adequately documented. Nurse Practitioners should check both with their compliance department as well as their state-specific scope of services before independently billing for a VAD interrogation.

It is incumbent upon the physician to determine which, if any modifiers should be used first.

Effective Dates: January 1, 2020 - December 31, 2020

CODING AND REIMBURSEMENT FOR LVAD

Hospital Inpatient[2]

CPT‡ CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
LEFT VENTRICULAR ASSIST DEVICE (LVAD) IMPLANT FOR HEARTMATE II™ LVAD AND HEARTMATE 3™ LVAD			
02HA0QZ	Insertion of implantable heart assist system into heart, open approach	001 Heart transplant or implant of heart assist system with MCC	$172,960
		002 Heart transplant or implant of heart assist system without MCC	$87,711

CMS restricts chronic and acute mechanical circulatory support procedures to the inpatient hospital site of service. Regardless of how many procedures are furnished, a single hospitalization receives a single MS-DRG payment. For Medicare beneficiaries, per CMS Program Transmittal 613, inpatient reimbursement for LVAD accessories and supplies is included in the MS-DRG payment to hospitals for the implant admission. 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. Replacement accessories and supplies are payable in the physician office or hospital outpatient setting, and are not considered Durable Medical Equipment per CMS Program Transmittal 1159.

Effective Dates: October 1, 2019 - September 30, 2020

CODING AND REIMBURSEMENT FOR LVAD

LVAD Replacement Supply and Accessory Codes[4]

HCPCS	DESCRIPTION	MEDICALLY UNLIKELY EDIT**	DMEPOS FEE SCHEDULE NATIONAL AVG
LVAD REPLACEMENT ACCESSORIES AND SUPPLIES - HOSPITAL OUTPATIENT OR PHYSICIAN OFFICE SETTING*			
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$751
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type	1	$178
Q0479	Power module for use with electric/pneumatic ventricular assist device, replacement only	1	$11,600
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only	1	$14,387
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only	1	$18,564
Q0486	Monitor control cable for use with electric ventricular assist device, replacement only	1	$290
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only	1	$16,094
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only	1	$1,094
Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$4,136

*DMEPOS fee schedule is updated on a quarterly basis and providers are encouraged to check the most recent DMEPOS fee schedule on CMS's website. If you have a question on the most recent payment rates for your locality, please email VADReimbursement@abbott.com for more information. These HCPCS codes all have coverage and payment jurisdiction with the local Medicare Administrative Contractor (MAC); they do not have coverage and payment jurisdiction at the DMEMAC. The HCPCS codes listed above have a defined DMEPOS fee schedule payment rate with the exception of HCPCS Q0508 and Q0509 whose payment rate is based on individual consideration with the local Medicare contractor. HCPCS Q0508 and Q0509 will require an invoice and supporting documentation for payment consideration. The Medically Unlikely Edit (MUE) for HCPCS code Q0508 (usually reported for driveline stabilization systems) is "24" units for outpatient hospital providers. CMS is working to ensure the same MUE edit for Q0508 furnished by practitioners and we will provide an update when that becomes available. Q0509 is reported for anything provided for a Medicare patient who was not a Medicare beneficiary at the time of LVAD implant.

All items must have documentation of medical necessity for payment; if any item not under warranty is lost, stolen, or damaged prior to one year post discharge, the-RA modifier should be used.

**Medically Unlike Edits (MUEs) are updated on a quarterly basis on CMS's website. The MUEs reflected in this guide are based on the date of service edits for Q4 2019. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html

Effective Dates: October 2019

CODING AND REIMBURSEMENT FOR LVAD

LVAD Replacement Supply Codes[4]

HCPCS	DESCRIPTION	MEDICALLY UNLIKELY EDIT**	DMEPOS FEE SCHEDULE NATIONAL AVG
LVAD REPLACEMENT ACCESSORIES AND SUPPLIES - HOSPITAL OUTPATIENT OR PHYSICIAN OFFICE SETTING*			
Q0496	Battery for use with electric or electric/pneumatic ventricular assist device, replacement only (excludes Li-Ion)	1	$1,484
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only	2	$464
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$509
Q0499	Belt/vest/bag for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$165
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$506
Q0506	Lithium Ion battery for use with electric or electric/pneumatic ventricular assist device, replacement only	8	$846
Q0508	Miscellaneous supply or accessory for use with any implanted ventricular assist device	4: physician's office 24: outpatient hospital	Paid on invoice
Q0509	Miscellaneous supply or accessory for use with implanted ventricular assist device for which payment was not made under Medicare Part A	2	Paid on invoice

*DMEPOS fee schedule is updated on a quarterly basis and providers are encouraged to check the most recent DMEPOS fee schedule on CMS's website. If you have a question on the most recent payment rates for your locality, please email VADReimbursement@abbott.com for more information. These HCPCS codes all have coverage and payment jurisdiction with the local Medicare Administrative Contractor (MAC); they do not have coverage and payment jurisdiction at the DMEMAC. The HCPCS codes listed above have a defined DMEPOS fee schedule payment rate with the exception of HCPCS Q0508 and Q0509 whose payment rate is based on individual consideration with the local Medicare contractor. HCPCS Q0508 and Q0509 will require an invoice and supporting documentation for payment consideration. The Medically Unlikely Edit (MUE) for HCPCS code Q0508 (usually reported for driveline stabilization systems) is "24" units for outpatient hospital providers. CMS is working to ensure the same MUE edit for Q0508 furnished by practitioners and we will provide an update when that becomes available. Q0509 is reported for anything provided for a Medicare patient who was not a Medicare beneficiary at the time of LVAD implant.

All items must have documentation of medical necessity for payment; if any item not under warranty is lost, stolen, or damaged prior to one year post discharge, the-RA modifier should be used.

**Medically Unlike Edits (MUEs) are updated on a quarterly basis on CMS's website. The MUEs reflected in this guide are based on the date of service edits for Q4 2019. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html

Effective Dates: October 2019

CODING AND REIMBURSEMENT FOR LVAD

HeartMate II™ LVAD and HeartMate 3™ LVAD Supply and Accessory HCPCS Crosswalk[3]

HEARTMATE II™ LVAD	HEARTMATE 3™ LVAD	DESCRIPTION	HCPCS
PART NUMBERS			
106762	106531US	Pocket Controller including emergency back-up battery	Q0481
106128	106128	Backup Battery for (11v) (for controller)	Q0506
107754	107754	Mobile Power Unit™	Q0479
1340	1340	Power Module	Q0479
103426	103426	Power Module Patient Cable	Q0477
1286	1286	Display Module	Q0483
2865	2865	14V Battery Clips (set of 2)	Q0497
2465	2465	14V Batteries (set of 4)	Q0506
104229, 30, 31	104229, 30, 31	HeartMate™ LVAD Holster Vest, (small, medium, large)	Q0498
104232	104232	HeartMate™ LVAD Shower Bag	Q0501
104234	104234	HeartMate™ LVAD Battery Holster	Q0498
1440	1440	Universal Battery Charger (UBC)	Q0495

Effective Dates: January 1, 2020 - December 31, 2020

CODING AND REIMBURSEMENT FOR LVAD

HeartMate II™ LVAD and HeartMate 3™ LVAD Supply and Accessory HCPCS Crosswalk[3]

HEARTMATE II™ LVAD	HEARTMATE 3™ LVAD	DESCRIPTION	HCPCS
PART NUMBERS			
1260	1260	HeartMate™ LVAD Travel Bag	Q0508
100760	NA	HeartMate II™ LVAD Stabilization Belts	Q0508
104233 106449	104233 106449	HeartMate™ LVAD Consolidated Bag, (right, left)	Q0499
NA	NA	Driveline Management System (e.g., dressings)	Q0508

Effective Dates: January 1, 2020 - December 31, 2020

CODING AND REIMBURSEMENT FOR LVAD

ICD-10CM Diagnosis Codes[5]

Diagnosis codes are used by both hospitals and physicians to document the medical necessity of the procedure. For Mechanical Circulatory Support patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The limited diagnosis list is not meant to be an exhaustive representation of the diagnosis options for the procedure. It is always the responsibility of health care providers to choose the most appropriate diagnosis code(s) representative of the patient's clinical condition. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10CM diagnosis codes.

ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY	
I23.0 - I23.9	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)
I50.1 - I50.9	Heart failure
I97.0	Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.120	Postprocedural cardiac arrest following cardiac surgery
I97.130	Postprocedural heart failure following cardiac surgery

ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY	
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
R57.0	Cardiogenic shock
T82.897	Other specified complication of cardiac prosthetic devices, implants and grafts
T86.298	Other complications of heart transplant
Z76.82	Awaiting organ transplant status (awaiting heart transplant)
Z95.811	Presence of heart assist device

Effective Dates: January 1, 2020 - December 31, 2020

CODING AND REIMBURSEMENT FOR LVAD

Coverage for HeartMate 3™ LVAD

The HeartMate 3™ Left Ventricular Assist Device (LVAD) is indicated to provide short and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure. The indication for "short-term and long-term support" falls within the national coverage determination (NCD) for ventricular assist devices (NCD 20.9.1) when appropriate criteria for bridge to transplant and destination therapy are met. To access the full NCD, https://www.cms.gov/medicare-coverage-database/

Most commercial payer policies reflect similar guidance as the Medicare NCD, but it is important that providers and institutions check their payer policies and seek prior authorization to ensure appropriate adherence to their LVAD coverage criteria. The coding, coverage, and payment for the HeartMate 3™ LVAD is the same as the HeartMate II™ LVAD.

ABBOTT CODING GUIDE

ACUTE MECHANICAL CIRCULATORY SUPPORT

Effective January 1, 2020

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE FACILITY
ACUTE MCS SYSTEM IMPLANT			
33975	Insertion of ventricular assist device; extracorporeal, single ventricle	25.00	$1,367
33976	Insertion of ventricular assist device; extracorporeal, biventricular	30.75	$1,662
ACUTE MCS SYSTEM REMOVAL			
33977	Removal of ventricular assist device; extracorporeal, single ventricle	20.86	$1,177
33978	Removal of ventricular assist device; extracorporeal, biventricular	25.00	$1,392
ACUTE MCS SYSTEM REPLACEMENT			
33981	Replacement of extracorporeal ventricular assist device; single or biventricular, pump(s), single or each pump	16.11	$871

The CPT‡ codes above describe possible surgeon services in the hospital inpatient setting where the Acute MCS system procedure (e.g., CentriMag™ or PediMag™ Pumps) occurs. These services are restricted to the inpatient hospital site of service.

PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump.

It is incumbent upon the physician to determine which, if any modifiers should be used first.

Effective Dates: January 1, 2020 - December 31, 2020

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

Hospital Inpatient[2]

ICD-10 PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL APPROACH			
02HA0RJ*	Insertion of Short-term External Heart Assist System into Heart, Intraoperative, Open Approach	215 Other heart assist system implant	$80,653
02HA0RZ*	Insertion of Short-term External Heart Assist System into Heart, Open Approach		
02HA3RJ*	Insertion of Short-term External Heart Assist System into Heart, Intraoperative, Percutaneous Approach		
02HA3RZ*	Insertion of Short-Term External Heart Assist System into Heart, Percutaneous Approach		
COMMON CLINICAL SCENARIOS FOR ACUTE MCS SYSTEM - EXTERNAL SHORT-TERM VAD PLACED			
Case A	Acute MCS system is place. Specify and document clinical approach.		MS-DRG 215
Case B	Acute MCS system is placed. Patient is transferred to another hospital		MS-DRG 215 (prorated- See Medicare payment for hospital transfers)

*It is important to document and code the CentriMag™ acute circulatory support system as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

Medicare Payment for Hospital Transfers

All MS-DRGs are subject to the CMS Transfer Policy with exception of MS-DRG 789. MS-DRG 789 assumes a transfer as part of its definition.

According to the CMS manuals, the transferring hospital receives a per diem, prorated from the expected MS-DRG. The per diem is derived from the MS-DRG's average length of stay when the transferring facility submits a claim to Medicare with the discharge status code of 02, "discharged/transferred to another short term general hospital for inpatient care." The geometric mean length of stay (LOS) and arithmetic mean LOS in FY2020 for MS-DRG 215 are 4.9 and 8.0 days, respectively.

The second hospital can expect full MS-DRG payment, even if the MS-DRG assignment turns out to be different from the transferring hospital. Hospital-specific factors-such as an ownership relations between the transferring and receiving hospital-could affect payment.

MS-DRG 215 is not subject to the "Postacute Care Transfers" policy.

Find CMS Hospital Manual language transfers in Chapter 3 Section 40.2.4 of the CMS Claims Processing Manual.

PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump.

Effective Dates: October 1, 2019 - September 30, 2020

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

ICD-10CM Diagnosis Codes[5]

Diagnosis codes are used by both hospitals and physicians to document the medical necessity of the procedure. For Mechanical Circulatory Support patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The limited list represented below is not meant to be an exhaustive representation of diagnosis options for the procedure. It is always the responsibility of health care providers to choose the most appropriate diagnosis code(s) representative of the patients' clinical condition. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10CM diagnosis codes.

ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY	
I23.0 - I23.9	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)
I50.1 - I50.9	Heart failure
I97.0	Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.120	Postprocedural cardiac arrest following cardiac surgery
I97.130	Postprocedural heart failure following cardiac surgery

ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY	
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
R57.0	Cardiogenic shock
T82.897	Other specified complication of cardiac prosthetic devices, implants and grafts
T86.298	Other complications of heart transplant
Z76.82	Awaiting organ transplant status (awaiting heart transplant)
Z95.811	Presence of heart assist device

PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump.

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 patients with advanced refractory left ventricular heart failure.

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 include, but are not limited to those 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 pump pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and pump thrombosis.

IMPORTANT SAFETY INFORMATION

Rx Only

Important Safety Information

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.

CentriMag™ Circulatory Support System Indications [PMA Approval; 30-day use]: Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.

CentriMag Circulatory Support System Contraindications [PMA Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

Humanitarian Device Statement: Caution: Humanitarian Device. The CentriMag™ Circulatory Support System is authorized by Federal Law for temporary circulatory support for up to 30 days for patients in cardiogenic shock due to right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

CentriMag RVAS Indications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

CentriMag RVAS Contraindications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag Blood Pump Indications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

CentriMag Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

PediMag™ Blood Pump Indications for Use [510(k) Clearance; 6-hour use]: The PediMag Blood Pump is indicated for use with the CentriMag Circulatory Support System console and motor to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

PediMag Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The PediMag Blood Pump is contraindicated for use as a cardiotomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag™ Drainage (Venous) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use]: The CentriMag Drainage (Venous) Cannula is indicated for use with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

CentriMag Drainage (Venous) Cannula Kit Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative. The CentriMag Drainage (Venous) Cannula is not intended for peripheral cannulation.

CentriMag™ Return (Arterial) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use]: The CentriMag Return (Arterial) Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

CentriMag Return (Arterial) Cannula Kit Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative. The CentriMag Return (Arterial) Cannula is not intended for peripheral cannulation.

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

*PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump and any other pediatric components or accessories.

REFERENCES

1. Physician Prospective Payment-Final rule with Comment Period and Final CY2020 Payment Rates. CMS-1715-F: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descendingl
2. Hospital Inpatient Prospective Payment-FY 2020 Final Rule and Correction Notice Data Files CMS-1716-F: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending
3. MM3931: New HCPCS Codes and System Edits for Supplies and Accessories for Ventricular Assist Devices-Full Replacement of CR3762.(2013, February 11). MLN Matters, 3931. Retrieved from https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/index.html
4. DMEPOS Fee schedule 2019: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html
5. American Medical Association, *2020 ICD-10-CM: The Complete Official Codebook*. Edition 1; 2020.
6. CMS, 2019 Alpha-Numeric Index HCPS code set: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2019-Alpha-Numeric-HCPCS-File.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending
7. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals, FY2019. Federal Register (Vol 84). May 3, 2019: https://www.federalregister.gov/documents/2019/05/03/2019-08330/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

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