ACUTE MECHANICAL CIRCULATORY SUPPORT (MCS) CODING GUIDE

CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM INCLUDING THE CENTRIMAG™ BLOOD PUMP AND PEDIMAG™ BLOOD PUMP

Effective October 1, 2024



ACUTE MECHANICAL CIRCULATORY SUPPORT (MCS)

Effective October 1, 2024

INTRODUCTION

The Acute Mechanical Circulatory Support (MCS) Coding Guide is intended to provide hospital coding and reimbursement information for physicians regarding the CentriMagTM Acute Circulatory Support System including the CentriMagTM pump and the PediMagTM 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/ hf.html. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

DISCLAIMER

This material and the information contained herein is for general information purposes only and is not intended, and does not constitute, legal, reimbursement, business, clinical, or other advice. Furthermore, it is not intended to and does not constitute a representation or guarantee of reimbursement, payment, or charge, or that reimbursement or other payment will be received. It is not intended to increase or maximize payment by any payer. Abbott makes no express or implied warranty or guarantee that the list of codes and narratives in this document is complete or error-free. Similarly, nothing in this document should be viewed as instructions for selecting any particular code, and Abbott does not advocate or warrant the appropriateness of the use of 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. In addition, the customer should note that laws, regulations, and coverage policies are complex and are updated frequently and is subject to change without notice. The customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial, coding, or reimbursement specialist for any questions related to coding, billing, reimbursement, or any related issues. This material reproduces information for reference purposes only. It is not provided or authorized for marketing use.



COVERAGE FOR ACUTE CIRCULATORY SUPPORT SYSTEM

Acute Mechanical Circulatory Support Systems, such as the CentriMag[™] device, are generally covered as a medically necessary procedure under most commercial payer policies for Mechanical Circulatory Assist Devices (Ventricular Assist Devices, Percutaneous Ventricular Assist Devices and Artificial Hearts). These commercial policies have been long-established as a clinically efficacious treatment for temporary circulatory support for individuals who have limited options for short-term cardiac support to improve function of the native heart as part of life-sustaining therapy. The Centers for Medicare and Medicaid Services (CMS) does not have a national coverage determination (NCD) for external heart assist procedures involving technologies like CentriMag and coverage is based on medical necessity. It is strongly encouraged that you verify with your local and commercial payer policies to ensure medical appropriateness.

ECMO

Please refer to the last page for Important Safety Information for CentriMagTM Acute Circulatory Support System and PediMagTM Blood Pump.

TYPE OF SUPPORT	REGULATORY PATHWAY	INDICATION
Extracorporeal Membrane Oxygenation (ECMO)	510(k) Clearance	Periods greater than six hours to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent*
Left ventricular support	PMA Approval	Up to 30 days to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass*
Dight wonthiaulan aunnant	PMA Approval	Up to 30 days to treat post-cardiotomy patients who fail to wean from cardio-pulmonary bypass*
Right ventricular support	Humanitarian Device Exemption	Up to 30 days for patients in cardiogenic shock due to acute right ventricular failure*
Bi-ventricular support	PMA Approval	Up to 30 days to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass*
In use during Cardiopulmonary support	510(k) Clearance	Periods appropriate to cardiopulmonary bypass (up to six hours)

Abbott. CentriMag™ Acute Circulatory Support System. Indications, Safety & Warnings.

^{*} Excludes PediMagTM



CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

PHYSICIAN¹

CPT [‡] CODE	DESCRIPTION Output Description Output Description Output Description Descr	WORK RVU	NATIONAL MEDICARE FACILITY RATE
ACUTE A	ACS SYSTEM IMPLANT		
33975	Insertion of ventricular assist device; extracorporeal, single ventricle	25.00	\$1,249
33976	Insertion of ventricular assist device; extracorporeal, biventricular	30.75	\$1,508
ACUTE N	ACS SYSTEM REMOVAL		
33977	Removal of ventricular assist device; extracorporeal, single ventricle	20.86	\$1,078
33978	Removal of ventricular assist device; extracorporeal, biventricular	25.00	\$1,270

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.

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

Effective Dates: January 1, 2024 - December 31, 2024

HEALTH ECONOMICS & REIMBURSEMENT

INSERTION: EXTERNAL ASSIST DEVICE | INSERTION: BIVENTRICULAR | INSERTION: INTRAOPERATIVE | REVISION | REPLACEMENT

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY **SUPPORT SYSTEM**

HOSPITAL INPATIENT²

EXTERNAL ASSIST DEVICE SHORT-TERM HEART ASSIST SYSTEM

ICD-10 PCS CODE ⁴	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE A	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE		
02HA0RZ*	Insertion of Short-term External Heart Assist System into Heart, Open Approach		
CHOOSE THE A	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON DURATION OR SUPPORT TYPE	001 w/MCC	\$200,461
5A02116	Assistance with cardiac output using other pump, intermittent	002 w/o MCC	\$78,427
5A02216	Assistance with cardiac output using other pump, continuous		

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 FY2025 for MS-DRG 215 are 5.0 and 9.0 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.

^{*}The CentrimagTM Blood Pump is listed as a Short term external heart assist system in the heart and great vessels in the 2025 ICD-10 PCS code set under Appendix C: Device Key. It is important to document and code the CentrimagTM Acute Circulatory Support System as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

HEALTH ECONOMICS & REIMBURSEMENT INSERTION: EXTERNAL ASSIST DEVICE | INSERTION: BIVENTRICULAR | INSERTION: INTRAOPERATIVE | REVISION | REPLACEMENT

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

HOSPITAL INPATIENT²

BIVENTRICULAR SHORT-TERM EXTERNAL HEART ASSIST SYSTEM

ICD-10 PCS CODE ⁴	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE	E APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE		
02HA0RS*	Insertion of Biventricular Short-term External Heart Assist System into Heart, Open Approach		
CHOOSE THI	E APPROPRIATE ICD-10 PROCEDURE CODE BASED ON DURATION OR SUPPORT TYPE	215	477 2 00
5A02116	Assistance with cardiac output using other pump, intermittent	Other heart assist system implant	\$75,399
5A02216	Assistance with cardiac output using other pump, continuous	- -	

^{*}The Centrimag™ Blood Pump is listed as a Short term external heart assist system in the heart and great vessels in the 2025 ICD-10 PCS code set under Appendix C: Device Key. 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.

HEALTH ECONOMICS & REIMBURSEMENT INSERTION: EXTERNAL ASSIST DEVICE | INSERTION: BIVENTRICULAR | INSERTION: INTRAOPERATIVE | REVISION | REPLACEMENT

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

HOSPITAL INPATIENT²

INTRAOPERATIVE SHORT-TERM EXTERNAL HEART ASSIST SYSTEM*

ICD-10 PCS CODE ⁴	DESCRIPTION	USE OF CARDIAC CATHETERIZATION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE APP	PROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH AND SUPPORT TYPE			
CHOOSE THE A	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH TYPE		216 xxx/N/ICC	φ.co.co2
02HA0RJ*	Insertion of Short-term External Heart Assist System in Heart and Great Vessels, Intraoperative, Open Approach	Yes	216 w/MCC 217 w/CC 218 w/out CC/MCC	\$68,682 \$45,957 \$42,340
CHOOSE THE	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON SUPPORT TYPE			
5A02116	Assistance with cardiac output using other pump, intermittent	TN. T	219 w/MCC	\$55,064
5A02216	Assistance with cardiac output using other pump, continuous	No	220 w/ CC 221 w/out MCC	\$37,694 \$32,683

^{*}The qualifier "intraoperative" was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedure where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported."

^{**}Insertion approach and Support type do not take into consideration the utilization of cardiac catheterization. Cardiac Catheterization should be separately coded as appropriate and supported by the clinical documentation.

HEALTH ECONOMICS & REIMBURSEMENT INSERTION: EXTERNAL ASSIST DEVICE | INSERTION: BIVENTRICULAR | INSERTION: INTRAOPERATIVE | REVISION | REPLACEMENT

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

HOSPITAL INPATIENT²

REVISION SHORT TERM EXTERNAL HEART ASSIST SYSTEM

ICD-10 PCS CODE ⁴	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE TH	E APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL APPROACH		
02WA0RS	Revision of <u>Biventricular</u> Short-term External Heart Assist System in Heart, Open Approach	215 Other heart assist	\$75,399
02WA0RZ	Revision of Short-term External Heart Assist System in Heart, Open Approach	system implant	

^{*}The Centrimag™ Blood Pump is listed as a Short term external heart assist system in the heart and great vessels in the 2025 ICD-10 PCS code set under Appendix C: Device Key. 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.

HEALTH ECONOMICS & REIMBURSEMENT INSERTION: EXTERNAL ASSIST DEVICE | INSERTION: BIVENTRICULAR | INSERTION: INTRAOPERATIVE | REVISION | REPLACEMENT

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

HOSPITAL INPATIENT²

REPLACEMENT SHORT TERM EXTERNAL HEART ASSIST SYSTEM

ICD-10 PCS CODE ⁴	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THI	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL APPROACH		
02HA0RZ	Insertion of Short-term External Heart Assist System into Heart, Open Approach	001 w/MCC	\$200,461
0211110102	insertion of Short term Direction real tribble bystem into freart, open ripproach	002 w/out MCC	\$78,427

The Centrimag™ Blood Pump is listed as a Short term external heart assist system in the heart and great vessels in the 2025 ICD-10 PCS code set under Appendix C: Device Key. 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.

The presence of Major Complications and/or Co-morbidities (MCCs) diagnosis(es) determine whether the hospital payment maps to MS-DRG 001 or MS-DRG 002



CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

ICD-10-CM DIAGNOSIS CODES³

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-10-CM diagnosis codes.

ICD-10-CM	DESCRIPTION	ICD-10-CM	DESCRIPTION
ICD CODES THAT MAY APPLY		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)	I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I50.1 - I50.9	Heart failure	R57.0	Cardiogenic shock
197.0	Postcardiotomy syndrome	T82.897	Other specified complication of cardiac prosthetic devices, implants and grafts
I97.110	Postprocedural cardiac insufficiency following cardiac surgery	T86.298	Other complications of heart transplant
I97.120	Postprocedural cardiac arrest following cardiac surgery	Z76.82	Awaiting organ transplant status (awaiting heart transplant)
I97.130	Postprocedural heart failure following cardiac surgery	Z95.811	Presence of heart assist device



CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

PHYSICIAN¹

CPT [‡] CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE FACILITY RATE
EXTRAC	ORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT	(ECLS) PROVIDED BY PHYS	SICIAN
33946	Initiation, veno-venous	6.00	\$297
33947	Initiation, veno-arterial	6.63	\$329
33948	Daily management, each day, veno-venous	4.73	\$228
33949	Daily management, each day, veno-arterial	4.60	\$223

Per CPT, code initiation codes on day of initial service, daily management codes are excluded on day of initial service.

The codes presented are not an exhaustive list of the codes which represent the work associated with ECMO support. Please see the CPT‡ code handbook for additional codes which may be applicable to other components of the ECMO circuit.

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.

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

Effective Dates: January 1, 2024 - December 31, 2024

HEALTH ECONOMICS & REIMBURSEMENT

SCENARIOS DRG MAPPING

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE **OXYGENATION**

HOSPITAL INPATIENT²

DRG MAPPING FOR ECMO PROCEDURES				
TYPE OF ECMO SUPPORT	TYPICAL MS-DRG ASSISGNMENT	NATIONAL MEDICARE RATE		
Non-Intraoperative ECMO	003 ECMO	\$152,519		
Intraoperative ECMO		ECMO was in support of a surgical (O.R.) procedure and the primary surgical procedure drives DRG assignment		



DRG MAPPING | SCENARIOS

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

HOSPITAL INPATIENT²

Scenarios illustrated below are for example only. This does not constitute coding guidance. It is important to verify clinical scenarios with your providers and coders.

SCENARIO 1: PATIENT IS PLACED ON ECMO AND TRANSFERRED TO ANOTHER HOSPITAL

Transferring Hospital 003 (Prorated)*

Receiving Hospital 003 (Full)

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 FY2025 for MS-DRG 003 are 24 and 34 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.

Refer to the CMS Hospital Manual language on "Transfers" in Chapter 3 Section 40.2.4 of the CMS Claims Processing Manual.

SCENARIO 2 : PATIENT SUPPORTED INTRAOPERATIVELY WITH ECMO FOR O.R. PROCEDURE		
ICD-10-PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE		
Primary Surgical Code INTRAOPERATIVE ECMO	Major surgical procedure done in concert with intraoperative ECMO	ECMO was in support of a surgical (O.R.) procedure and the primary surgical procedure drives DRG assignment

Intraoperative ECMO procedures are designated as non-OR procedures. As such the MS DRG Assignment is driven by the primary surgical procedure.

Scenarios illustrated are for example only. This does not constitute coding guidance. It is important to verify clinical scenarios with your providers and coders. Coding scenarios were verified by AAPC certified coder.



CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

ICD-10-CM DIAGNOSIS CODES³

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-10-CM diagnosis codes.

ICD-10-CM	DESCRIPTION	ICD-10-C	M DESCRIPTION
ICD CODES THA	AT MAY APPLY	ICD CODES	S THAT MAY APPLY
I21.0 - I21.9	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	T82.857	Stenosis of other cardiac prosthetic devices, implants and grafts
A41.8	Other sepsis	I71.0	Aortic aneurysm and dissection
I25.10 – I25.119	Atherosclerotic heart disease of native coronary artery	J84.11	Idiopathic interstitial pneumonia
I50.1 - I50.9	Heart failure	J84.10	Other interstitial pulmonary diseases with fibrosis
I35.0	Nonrheumatic mitral valve disorders	J96.0	Acute respiratory failure
I35.0	Nonrheumatic aortic valve disorders	J96.2	Acute and chronic respiratory failure
I47.0	Paroxysmal tachycardia		



CentriMAG™ Circulatory Support System Important Safety Indications

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.

CentriMagTM 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.

CentriMag™ Circulatory Support System Adverse Events [PMA Approval; 30-day use]: Adverse events that may be associated with mechanical circulatory support can include, but are not limited to, the following: bleeding on device support, hemolysis, infection, renal failure/dysfunction/complication, respiratory dysfunction, cardia arrhythmias (atrial or ventricular), thromboembolism (venous and arterial non-CNS), hypotension, hypertension, device malfunction or failure, psychiatric events, right heart failure, and death.

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.

CentriMagTM 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.

CentriMagTM 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[™] Acute Circulatory Support System Temporary Expanded Indication: The FDA issued an enforcement policy guidance document in April 2020 allowing for FDA-cleared or approved cardiopulmonary bypass devices to be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency. The CentriMag[™] System including the CentriMag[™] Blood Pump and PediMag[™] Blood Pump are indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure.

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.

CentriMagTM Blood Pump Indication [ECMO, 510(k) Clearance; >6-hour use]: The CentriMagTM Blood Pump for use with the CentriMagTM Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

CentriMagTM Blood Pump Contraindications [ECMO, 510(k) Clearance; >6-hour use]: The CentriMagTM 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.



References

- 1. Physician Prospective Payment-Final rule with Comment Period and Final CY2024 Payment Rates. CMS-1784-F: https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f
- 2. CMS_2025_Hospital Inpatient Prospective Payment-Final Rule Home Page CMS-1808-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page
- 3. CMS 2025 ICD-10-CM: https://www.cms.gov/medicare/coding-billing/icd-10-codes/2025-icd-10-cm
- 4. CMS 2025 ICD-10-PCS Procedure Coding System and Index: https://www.cms.gov/medicare/coding-billing/icd-10-codes/2025-icd-10-pcs

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