



# ACUTE MECHANICAL CIRCULATORY SUPPORT (MCS) CODING GUIDE

## CENTRIMAG<sup>TM</sup> ACUTE CIRCULATORY SUPPORT SYSTEM INCLUDING THE CENTRIMAG<sup>TM</sup> BLOOD PUMP AND PEDIMAG<sup>TM</sup> BLOOD PUMP

Effective January 1, 2025

REFERENCES | SEE IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

#### COVERAGE/INDICATION | ACUTE VAD | **ECMO**







## **ACUTE MECHANICAL CIRCULATORY SUPPORT (MCS)**

Effective January 1, 2025

### INTRODUCTION

The Acute Mechanical Circulatory Support (MCS) Coding Guide is intended to provide hospital coding and reimbursement information for physicians regarding the CentriMag<sup>™</sup> Acute Circulatory Support System including the CentriMag<sup>™</sup> pump and the PediMag<sup>™</sup> 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.

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## **COVERAGE FOR ACUTE CIRCULATORY SUPPORT SYSTEM**

Acute Mechanical Circulatory Support Systems, such as the CentriMag<sup>TM</sup> 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.

Please refer to the last page for Important Safety Information for CentriMag<sup>™</sup> Acute Circulatory Support System and PediMag<sup>™</sup> Blood Pump.

**REGULATORY PATHWAY TYPE OF SUPPORT** Extracorporeal Membrane Oxygenation 510(k) Clearance (ECMO) Left ventricular support PMA Approval PMA Approval Right ventricular support Humanitarian Device Exe Bi-ventricular support PMA Approval In use during Cardiopulmonary support 510(k) Clearance

Abbott. CentriMag<sup>™</sup> Acute Circulatory Support System. Indications, Safety & Warnings. \* Excludes PediMag<sup>TM</sup>

•	INDICATION
	Periods greater than six hours to provide assisted extracorporeal of and physiologic gas exchange of the patients' blood for adult patie acute respiratory failure and/or acute cardiopulmonary failure, wh available treatment options have failed, and continued clinical det expected or the risk of death is imminent*
	Up to 30 days to treat post-cardiotomy patients who fail to wean f cardiopulmonary bypass*
	Up to 30 days to treat post-cardiotomy patients who fail to wean fr pulmonary bypass*
xemption	Up to 30 days for patients in cardiogenic shock due to acute right failure*
	Up to 30 days to treat post-cardiotomy patients who fail to wean fr cardiopulmonary bypass*
	Periods appropriate to cardiopulmonary bypass (up to six hours)

circulation ients with where other eterioration is

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from



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

### PHYSICIAN<sup>1</sup>

CPT <sup>‡</sup> CODE	DESCRIPTION
ACUTE N	CS SYSTEM IMPLANT
33975	Insertion of ventricular assist device; extracorporeal, single
33976	Insertion of ventricular assist device; extracorporeal, biven
ACUTE N	ICS SYSTEM REMOVAL
33977	Removal of ventricular assist device; extracorporeal, single
33978	Removal of ventricular assist device: extracorporeal, bivent

The CPT‡ codes above describe possible surgeon services in the hospital inpatient setting where the Acute MCS system procedure (e.g., CentriMag<sup>™</sup> or PediMag<sup>™</sup> 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.

	WORK RVU	NATIONAL FACILIT
le ventricle	25.00	\$1,24
ntricular	30.75	\$1,4
e ventricle	20.86	\$1,0
ntricular	25.00	\$1,2

Effective Dates: January 1, 2025 - December 31, 2025



## **MEDICARE** YRATE 240 494

071

262

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

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

HOSPITAL INPATIENT<sup>2</sup>

### EXTERNAL ASSIST DEVICE SHORT-TERM HEART ASSIST SYSTEM

ICD-10 PCS CODE <sup>4</sup>	DESCRIPTION
CHOOSE THE A	PPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TY
02HA0RZ*	Insertion of Short-term External Heart Assist System into He
CHOOSE THE A	PPROPRIATE ICD-10 PROCEDURE CODE BASED ON DURATION O
5A02116	Assistance with cardiac output using other pump, intermitten
5A02216	Assistance with cardiac output using other pump, continuous

\*The Centrimag<sup>TM</sup> 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<sup>TM</sup> Acute Circulatory Support System as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

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.

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

REFERENCES | SEE IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

#### COVERAGE/INDICATION **ACUTE VAD ECMO** PHYSICIAN INPATIENT ADDITIONAL CODES

ION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RA
LINICAL TYPE		
em into Heart, Open Approach		
URATION OR SUPPORT TYPE	$001 \mathrm{w/MCC}$	\$201,024
ntermittent	002 w/o MCC	\$78,642
ontinuous		

Effective Dates: October 1, 2024 - September 30, 2025

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### ATIONAL CARE RATE



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

HOSPITAL INPATIENT<sup>2</sup>

### **BIVENTRICULAR SHORT-TERM EXTERNAL HEART ASSIST SYSTEM**

ICD-10 PCS CODE <sup>4</sup>	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	N. MED
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 TH	E APPROPRIATE ICD-10 PROCEDURE CODE BASED ON DURATION OR SUPPORT TYPE	215	
5A02116	Assistance with cardiac output using other pump, intermittent	Other heart assist system implant	
5A02216	Assistance with cardiac output using other pump, continuous	- <b>v i</b>	

\*The Centrimag<sup>TM</sup> 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<sup>TM</sup> acute circulatory support system as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

#### COVERAGE/INDICATION ECMO ACUTE VAD PHYSICIAN | INPATIENT | ADDITIONAL CODES







#### \$75,610

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

HOSPITAL INPATIENT<sup>2</sup>

### INTRAOPERATIVE SHORT-TERM EXTERNAL HEART ASSIST SYSTEM\*

ICD-10 PCS CODE <sup>4</sup>	DESCRIPTION	USE OF CARDIAC CATHETERIZATION	TYPICAL MS-DRG ASSIGNMENT	NAT MEDIC
CHOOSE THE API	PROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH AND SUPPORT TYPE			
CHOOSE THE /	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH TYPE		216 w/MCC	<u>ተ</u> ረ
02HA0RJ*	Insertion of Short-term External Heart Assist System in Heart and Great Vessels, Intraoperative, Open Approach		210 w/MCC 217 w/CC 218 w/out CC/MCC	\$68 \$40 \$42
CHOOSE THE	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON SUPPORT TYPE			
5A02116	Assistance with cardiac output using other pump, intermittent	N T -	219 w/MCC	\$5
5A02216	Assistance with cardiac output using other pump, continuous	No	220 w/ CC 221 w/out MCC	\$32 \$32

ICD-10 PCS CODE <sup>4</sup>	DESCRIPTION	USE OF CARDIAC CATHETERIZATION	TYPICAL MS-DRG ASSIGNMENT	NAT MEDIC
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 w/MCC	ф. <i>с</i> .
02HAORJ*	Insertion of Short-term External Heart Assist System in Heart and Great Vessels, Intraoperative, Open Approach			\$68 \$40 \$42
CHOOSE THE	APPROPRIATE ICD-10 PROCEDURE CODE BASED ON SUPPORT TYPE			
5A02116	Assistance with cardiac output using other pump, intermittent		219 w/MCC	\$5
5A02216	Assistance with cardiac output using other pump, continuous	No	220 w/ CC 221 w/out MCC	\$32 \$32

\*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 procedures 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.

#### COVERAGE/INDICATION ECMO **ACUTE VAD** PHYSICIAN INPATIENT ADDITIONAL CODES



## TIONAL CARE RATE

68,875 46,087 42,457

55,219 37,800 32,775

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

HOSPITAL INPATIENT<sup>2</sup>

### **REVISION SHORT TERM EXTERNAL HEART ASSIST SYSTEM**

**ICD-10** PCS CODE<sup>4</sup>

DESCRIPTION

CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CL

- Revision of **Biventricular** Short-term External Heart As 02WAORS Open Approach
- Revision of Short-term External Heart Assist System in Heart, Open Approach 02WA0RZ

\*The Centrimag<sup>TM</sup> 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<sup>TM</sup> acute circulatory support system as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

#### COVERAGE/INDICATION **ACUTE VAD ECMO** PHYSICIAN INPATIENT ADDITIONAL CODES

	TYPICAL MS-DRG ASSIGNMENT	NATIO MEDICA
INICAL APPROACH		
Assist System in Heart,	215 Other heart assist	\$75
n Heart-Open Approach	system implant	







### 75,610

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

HOSPITAL INPATIENT<sup>2</sup>

### REPLACEMENT SHORT TERM EXTERNAL HEART ASSIST SYSTEM

**ICD-10** PCS CODE<sup>4</sup>

DESCRIPTIO

CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CL

Insertion of Short-term External Heart Assist System in 02HAORZ

The Centrimag<sup>™</sup> 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<sup>™</sup> 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

#### COVERAGE/INDICATION **ACUTE VAD** ECMO PHYSICIAN INPATIENT ADDITIONAL CODES

N	TYPICAL MS-DRG ASSIGNMENT	NATI MEDICA
LINICAL APPROACH		
into Heart, Open Approach	001 w/MCC	\$20
meo meare, open approach	002 w/out MCC	\$78

Effective Dates: October 1, 2024- September 30, 2025







#### 01,024

8,642

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

### ICD-10-CM DIAGNOSIS CODES<sup>3</sup>

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 CODES TH	AT MAY APPLY
I23.0 - I23.9	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocard infarction (within the 28 day period)
I50.1 - I50.9	Heart failure
I97.0	Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardi surgery
I97.120	Postprocedural cardiac arrest following cardiac surg
I97.130	Postprocedural heart failure following cardiac surge

	ICD-10-CM	DESCRIPTION
	ICD CODES TH	
on dial	I97.190	Other postprocedural cardiac functional disturbation following cardiac surgery
	R57.0	Cardiogenic shock
	T82.897	Other specified complication of cardiac prosthet implants and grafts
iac	T86.298	Other complications of heart transplant
gery	Z76.82	Awaiting organ transplant status (awaiting heart
ery	Z95.811	Presence of heart assist device

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### **CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION**

### PHYSICIAN<sup>1</sup>

CPT <sup>‡</sup> CODE	DESCRIPTION	WORK RVU	NATIONAL MEDIC FACILITY RATE		
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN					
33946	Initiation, veno-venous	6.00	\$294		
33947	Initiation, veno-arterial	6.63	\$326		
33948	Daily management, each day, veno-venous	4.73	\$228		
33949	Daily management, each day, veno-arterial	4.60	\$222		

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<sup>‡</sup> codes above describe possible surgeon services in the hospital inpatient setting where the Acute MCS system procedure (e.g., CentriMag<sup>TM</sup> or PediMag<sup>TM</sup> 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.

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HEALTH ECONOMICS & REIMBURSEMENT

### **CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION**

HOSPITAL INPATIENT<sup>2</sup>

DRG MAPPING FOR ECMO PROCEDURES

**TYPE OF ECMO SUPPORT** 

Non-Intraoperative ECMO

**TYPICAL MS-DRG ASSISGNMENT** NATIONAL MEDICARE RATE

003 ECMO

Intraoperative ECMO

SEE IMPORTANT SAFETY INFORMATION REFERENCED WITHIN REFERENCES

GE/INDICATION	ACUTE VAD	ECMO			
		PHYSICIAN	INPATIENT	ADDITION	

**SCENARIOS** DRG MAPPING

\$152,947

ECMO was in support of a surgical (O.R.) procedure and the primary surgical procedure drives DRG assignment

#### NAL CODES

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### **CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION**

### HOSPITAL INPATIENT<sup>2</sup>

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

#### **Receiving Hospital**

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

#### CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE

Primary Surgical Code

Major surgical procedure done in concert with intraoperative ECMO

#### **INTRAOPERATIVE ECMO**

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.

**SCENARIOS** DRG MAPPING

003 (Prorated)\*

003 (Full)

#### **TYPICAL MS-DRG ASSIGNMENT**

ECMO was in support of a surgical (O.R.) procedure and the primary surgical procedure drives DRG assignment

#### **INPATIENT** ADDITIONAL CODES

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## **CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION**

### ICD-10-CM DIAGNOSIS CODES<sup>3</sup>

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 or financial counsel, 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 THA	T MAY APPLY	ICD CODES T	HAT MAY APPLY
	I21.0 - I21.9	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	T82.857	Stenosis of other cardiac prosthetic devices, implagrafts
	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 fibrosi
	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		

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#### **CentriMAG<sup>TM</sup>** 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.

CentriMag<sup>™</sup> 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<sup>™</sup> Circulatory Support System Contraindications [PMA Approval; 30-day use]: The CentriMag<sup>™</sup> 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, hepatic 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.

CentriMag<sup>TM</sup> 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<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> System including the CentriMag<sup>™</sup> Blood Pump and PediMag<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> Blood Pump Indication [ECMO, 510(k) Clearance; >6-hour use]: The CentriMag<sup>™</sup> Blood Pump for use with the CentriMag<sup>™</sup> 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.

**CentriMag<sup>TM</sup> Blood Pump Contraindications [ECMO, 510(k) Clearance; >6-hour use]**: The CentriMag<sup>TM</sup> 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 **SEE IMPORTANT SAFETY INFORMATION REFERENCED WITHIN** 

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#### References

- 1. Physician Prospective Payment-Final rule with Comment Period and Final CY2025 Payment Rates. CMS-1807-F: https://www.cms.gov/medicare/ payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f
- 2. CMS\_2025\_Hospital Inpatient Prospective Payment-Final Rule Home Page CMS-1808-F: https://www.cms.gov/medicare/payment/prospectivepayment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page
- 3. CMS 2025 ICD-10-CM: https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf
- 4. CMS 2025 ICD-10-PCS: https://www.cms.gov/files/document/2025-official-icd-10-pcs-coding-guidelines.pdf

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www.cardiovascular.abbott www.cardiovascular.abbott/CentriMag

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#### COVERAGE/INDICATION ACUTE VAD ECMO

