ABBOTT CODING GUIDE

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

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

Effective April 6, 2020

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

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Introduction

The Extracorporeal Membrane Oxygenation (ECMO) Coding Guide is intended to provide coding and reimbursement information for physicians and hospitals regarding the emergency use authorization for the CentriMag™ Acute Circulatory Support System including the CentriMag ™ pump and the PediMag ™ pump procedures. For coding and reimbursement information regarding utilization of the CentriMag ™ Acute Circulatory Support System for ventricular support, please visit:
cardiovascular.abbott/us/en/hcp/reimbursement.html

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:
cardiovascular.abbott/us/en/hcp/reimbursement.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.

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)

The provided terms and definitions are to assist with the language utilized in the codes that support ECMO procedures per CMS definitions. This is not an exhaustive list of terms that pertain to ECMO. For additional terms please visit: https://www.elso.org/Resources/GlossaryofTerms.aspx

EXTRACORPOREAL MEMBRANE OXYGENATION

ECMO is an advanced life support technique used in critically ill patients who are felt to have severe cardiopulmonary insufficiency that has not responded to conventional management. While on ECMO, a patient's blood is continuously circulated from the body through the ECMO machine where it is oxygenated and then returned back into the patient, thus temporarily replacing lung function (e.g., Veno-venous ECMO) or both heart and lung functions (e.g., Veno-arterial ECMO).

VA ECMO (VENO-ARTERIAL ECMO) (FIG 1)

A type of ECMO that drains blood from a vein, oxygenates the blood in the circuit, and returns the blood to the body through an artery. This type of ECMO can be used to support both the heart and lungs

VV ECMO (VENO-VENOUS ECMO) (FIG 2)

A type of ECMO that drains blood from a vein, oxygenates the blood in the circuit, and returns the blood through a vein. This type of ECMO is used when only the lungs need support

PERIPHERAL CANNULATION

insertion of cannulae via the femoral, cervical, or axillary vessels either by open surgical cutdown or percutaneously.

PERIPHERAL CANNULATION OPEN APPROACH

A technique of peripheral cannulation where a surgical cut down is utilized to access the femoral, cervical, or axillary vessels.

PERIPHERAL CANNULATION PERCUTANEOUS APPROACH

A technique of peripheral cannulation where access to the femoral, cervical, or axillary vessels is established percutaneously without a cutdown.

CENTRAL CANNULATION (FIG 3, VA ECMO SHOWN)

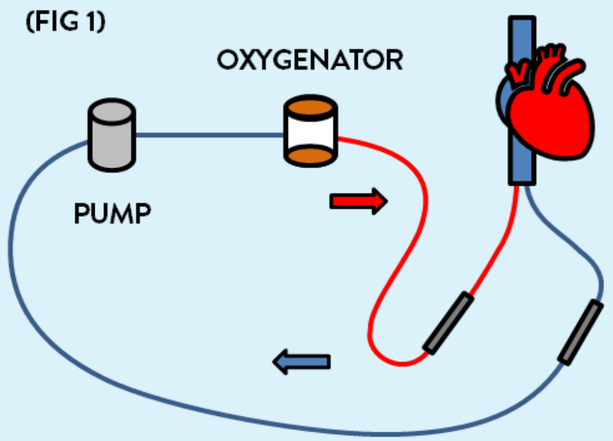
A technique of cannulation accomplished via insertion of cannulae directly into the cardiac chambers or great vessels.

INTRAOPERATIVE ECMO SUPPORT

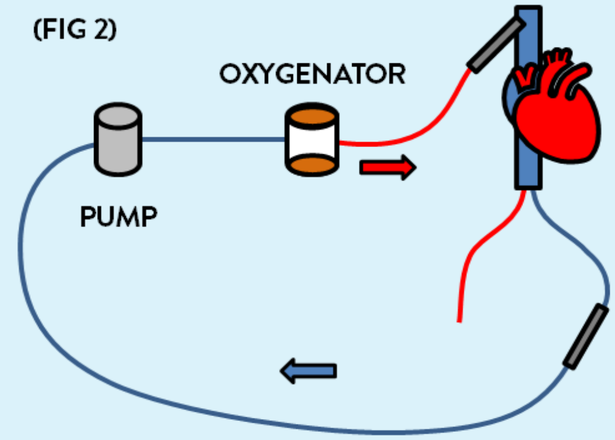
ECMO provided during the course of surgery

https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2019-ICD10-March-Agenda-Handouts.pdf

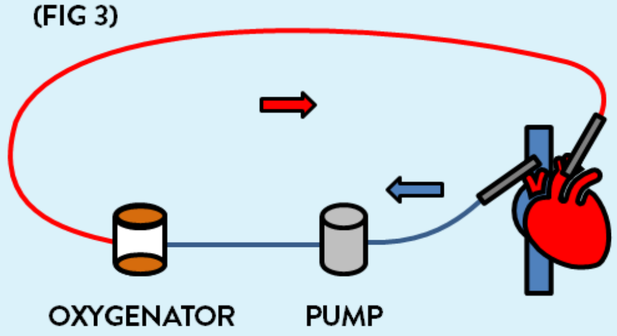
(FIG 1)



(FIG 2)



(FIG 3)



FDA EMERGENCY USE AUTHORIZATION (EUA) FOR ECMO SUPPORT

The FDA has issued an Emergency Use Authorization (EUA) allowing for Abbott's CentriMag ™ Acute Circulatory Support System to be used for extracorporeal membrane oxygenation (ECMO) support in treating critical care patients impacted by the novel coronavirus (COVID-19).

Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during

WHAT IS AN EUA?

An Emergency Use Authorization (EUA) allows the FDA to help strengthen the nation's public health protection by facilitating the availability and use of medical countermeasures needed during public health emergencies. This includes allowing unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when there are no adequate, approved, and available alternatives. This EUA will remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

MODIFICATIONS TO FDA CLEARED OR FDA APPROVED INDICATIONS OR DESIGN

For the duration of the public health emergency, FDA does not intend to object to modifications to the indications or design of FDA cleared or approved devices listed in Table 1 and Table 2 of the Enforcement Policy without prior submission of a premarket notification or premarket approval application supplement where the modification does not create an undue risk in light of the public health emergency. FDA currently believes a modification does not create such undue risk in the following scenarios:

1. For cardiopulmonary bypass devices, changes to the device's indications to include use of the device in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure;
2. **For cardiopulmonary bypass devices, changes to the device's indications regarding use of the device for longer than 6 hours in an ECMO circuit; or**
3. For both cardiopulmonary bypass devices and ECMO devices, changes to the dimension(s) of cannulae, tubing, filters, connectors, or other accessories to support use in an ECMO circuit that do not affect the flow rate of blood throughout the circuit.

Abbott. CentriMag™ Acute Circulatory Support System. Indications, Safety & Warnings.
https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/centrimag-acute-circulatory-support-system.html

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN;				
33951	Insertion of peripheral (arterial and/or venous) cannula(e), **percutaneous**, birth through 5 years of age (includes fluoroscopic guidance, when performed)	8.15	$444	NA
33952	Insertion of peripheral (arterial and/or venous) cannula(e), **percutaneous**, 6 years and older (includes fluoroscopic guidance, when performed)	8.15	$448	NA
33953	Insertion of peripheral (arterial and/or venous) cannula(e), **open**, birth through 5 years of age	9.11	$495	NA
33954	Insertion of peripheral (arterial and/or venous) cannula(e), **open**, 6 years and older	9.11	$499	NA
33955	Insertion of central cannula(e) by **sternotomy or thoracotomy**, birth through 5 years of age	16.00	$869	NA
33956	Insertion of central cannula(e) by **sternotomy or thoracotomy**, 6 years and older	16.00	$874	NA

Per CPT, insertion includes Cannula replacement in same vessel, and Cannula repositioning during the same episode of care

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN;				
33946	Initiation, veno-venous	6.00	$323	NA
33947	Initiation, veno-arterial	6.63	$359	NA
33948	Daily management, each day, veno-venous	4.73	$250	NA
33949	Daily management, each day, veno-arterial	4.60	$243	NA

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

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.

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CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN;				
33957	Reposition peripheral (arterial and/or venous) cannula(e), **percutaneous**, birth through 5 years of age (includes fluoroscopic guidance, when performed)	3.51	$193	NA
33958	Reposition peripheral (arterial and/or venous) cannula(e), **percutaneous**, 6 years and older (includes fluoroscopic guidance, when performed)	3.51	$193	NA
33959	Reposition peripheral (arterial and/or venous) cannula(e), **open**, birth through 5 years of age (includes fluoroscopic guidance, when performed)	4.47	$245	NA
33962	Reposition peripheral (arterial and/or venous) cannula(e), **open**, 6 years and older (includes fluoroscopic guidance, when performed)	4.47	$245	NA
33963	Reposition of central cannula(e) by **sternotomy or thoracotomy**, birth through 5 years of age (includes fluoroscopic guidance, when performed)	9.00	$490	NA
33964	Reposition central cannula(e) by **sternotomy or thoracotomy**, 6 years and older (includes fluoroscopic guidance, when performed)	9.50	$517	NA

Per CPT, do not report repositioning codes with initiation or insertion codes on same day of service

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN;				
33965	Removal of peripheral (arterial and/or venous) cannula(e), **percutaneous**, birth through 5 years of age	3.51	$193	NA
33966	Removal of peripheral (arterial and/or venous) cannula(e), **percutaneous**, 6 years and older	4.50	$248	NA
33969	Removal of peripheral (arterial and/or venous) cannula(e), **open**, birth through 5 years of age	5.22	$285	NA
33984	Removal of peripheral (arterial and/or venous) cannula(e), **open**, 6 years and older	5.46	$298	NA
33985	Removal of central cannula(e) by **sternotomy or thoracotomy**, birth through 5 years of age	9.89	$538	NA
33986	Removal of central cannula(e) by **sternotomy or thoracotomy**, 6 years and older	10.00	$548	NA

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Physician[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE	
			FACILITY	NON FACILITY
EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)/EXTRACORPOREAL LIFE SUPPORT (ECLS) PROVIDED BY PHYSICIAN;				
+33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)*	4.04	$218	NA
33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	15.00	$814	NA
33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS	9.50	$517	NA

*Per CPT, Use 33987 in conjunction with 33953, 33954, 33955, 33956

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

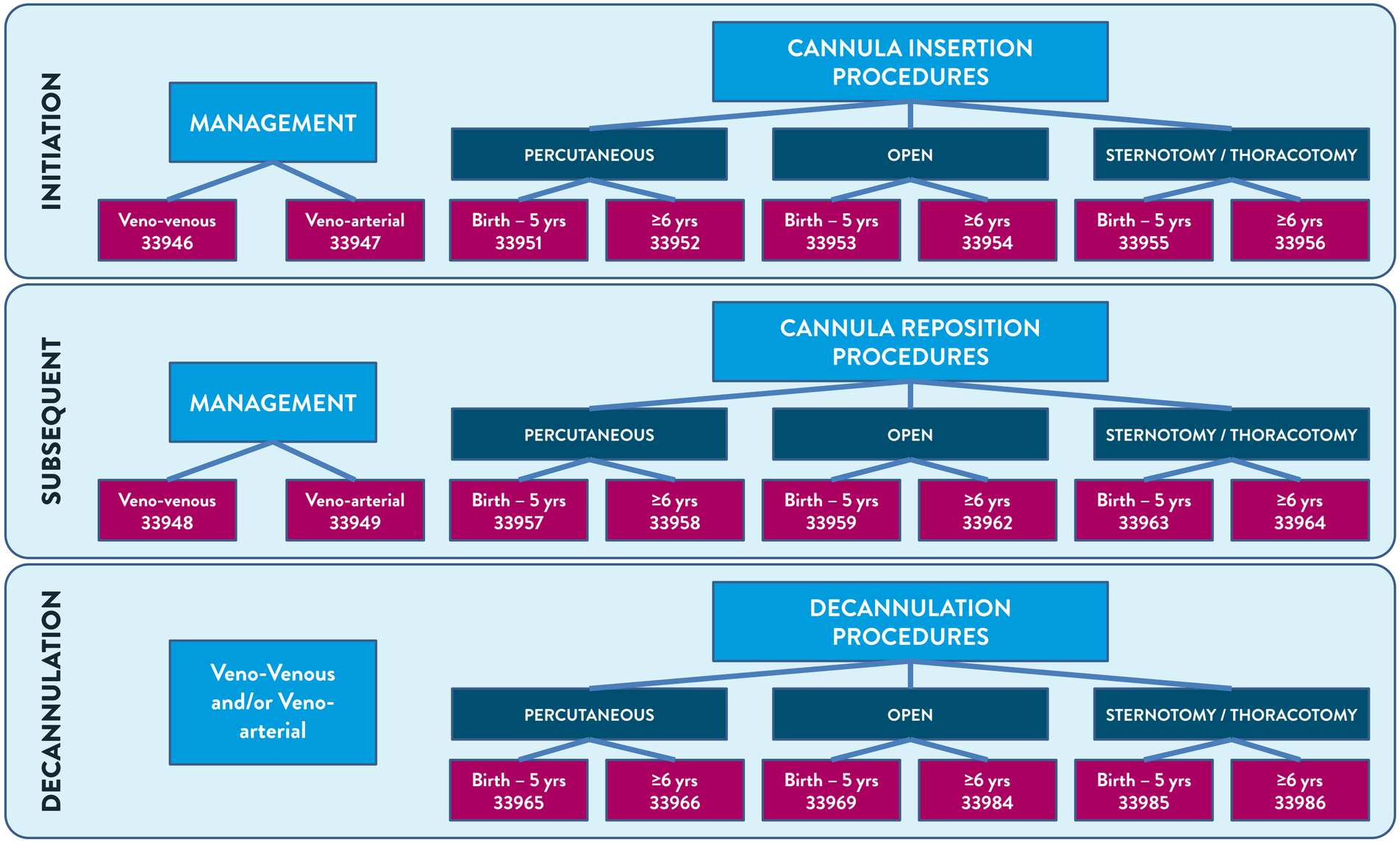

Diagram of scenarios obtained from CPT 2020

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Scenarios illustrated below are examples provided by the CPT introductory language on ECMO support. This does not constitute coding guidance. It is important to verify clinical scenarios with your providers and coders.

CANNULA(E) REMOVED FROM ONE VESSEL AND NEW CANNULA(E) ARE PLACED IN A DIFFERENT VESSEL IN SUPPORT OF ECMO	
CPT‡ CODE	**DESCRIPTION**
CHOOSE CODES BASED UPON SUPPORT TYPE	
33965/33966/33969/33984/33985/33986	Cannula(e) removal*
33951/33952/33953/33954/33955/33956	Cannula(e) insertion*

REPLACEMENT OF CANNULA(E) IN SAME VESSEL IN SUPPORT OF ECMO	
CPT‡ CODE	**DESCRIPTION**
CHOOSE CODES BASED UPON SUPPORT TYPE	
33951/33952/33953/33954/33955/33956	Cannula(e) insertion*

*Codes subject to Multiple Procedure Guidelines. Highest valued procedure: 100%, Second, third, fourth, and fifth valued procedures: 50% Each procedure beyond the fifth: By report

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.
A list of CPT‡ code modifiers can be found at cardiovascular.abbott/us/en/hcp/reimbursement.html

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Hospital Inpatient[2]

ICD-10 PCS CODE[4]	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE			
5A1522F	Extracorporeal Oxygenation, Membrane, Central	003 ECMO	$118,722
5A1522G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial		
5A1522H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous		
INTRAOPERATIVE ECMO SUPPORT			
5A15A2F	Extracorporeal Oxygenation, Membrane, Central, Intraoperative	ECMO was in support of a surgical (O.R.) procedure and the primary surgical procedure drives DRG assignment	
5A15A2G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative		
5A15A2H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative		

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Hospital Inpatient[2]

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 FY2020 for MS-DRG 003 are 22.9 and 30.4 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	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
+		
5A15A2F	Extracorporeal Oxygenation, Membrane, Central, Intraoperative	
5A15A2G	Extracorporeal Oxygenation, Membrane, Peripheral Veno-arterial, Intraoperative	
5A15A2H	Extracorporeal Oxygenation, Membrane, Peripheral Veno-venous, Intraoperative	

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

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

ICD-10-CM Diagnosis Codes[3]

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	
I21.0 – I21.9	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
A41.8	Other sepsis
I25.10 – I25.119	Atherosclerotic heart disease of native coronary artery
I50.1 - I50.9	Heart failure
I34.0	Nonrheumatic mitral valve disorders
I35.0	Nonrheumatic aortic valve disorders
I47.0	Paroxysmal tachycardia

ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY	
T82.857	Stenosis of other cardiac prosthetic devices, implants and grafts
I71.0	Aortic aneurysm and dissection
J84.11	Idiopathic interstitial pneumonia
J84.10	Other interstitial pulmonary diseases with fibrosis
J96.0	Acute respiratory failure
J96.2	Acute and chronic respiratory failure

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

CODING AND REIMBURSEMENT FOR EXTRACORPOREAL MEMBRANE OXYGENATION

Acute respiratory illness due to COVID-19[5]

On April 1, 2020 the CDC added a new ICD-10-CM code specifically for COVID-19 and guidance for reporting acute respiratory illnesses due to COVID-19
https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf

ICD-10-CM	DESCRIPTION
U07.1	COVID-19

PNEUMONIA

For a pneumonia case confirmed as due to the 2019 novel coronavirus (COVID-19), assign codes **U07.1, COVID-19**, and J12.89, Other viral pneumonia

ACUTE BRONCHITIS

For a patient with acute bronchitis confirmed as due to COVID-19, assign codes **U07.1**, and J20.8, Acute bronchitis due to other specified organisms. Bronchitis not otherwise specified (NOS) due to COVID-19 should be coded using code **U07.1** and J40, Bronchitis, not specified as acute or chronic.

ACUTE RESPIRATORY DISTRESS SYNDROME

For acute respiratory distress syndrome (ARDS) due to COVID-19, assign codes **U07.1**, and J80, Acute respiratory distress syndrome

LOWER RESPIRATORY INFECTION

If the COVID-19 is documented as being associated with a lower respiratory infection, not otherwise specified (NOS), or an acute respiratory infection, NOS, codes **U07.1** and J22, Unspecified acute lower respiratory infection, should be assigned. If the COVID-19 is documented as being associated with a respiratory infection, NOS, codes U07.1 and J98.8, Other specified respiratory disorders, should be assigned.

Reimbursement information regarding the ID NOW™ COVID-19 Assay is available at: https://www.codemap.com/alere/default.cfm?covid=y

Effective Dates: April 1, 2020 - September 2020

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=descending
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. American Medical Association, *2020 ICD-10-CM: The Complete Official Codebook.* Edition 1; 2020.
4. CMS ICD-10-P2020 CS Procedure Coding System and Index: https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-PCS.html
5. ICD-10-CM Official Coding Guidelines for COVID-19 April 1, 2020 -September 30, 2020. https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf

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.

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.

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