CMS Manual System	Department of Health & Human Services (DHHS)		
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)		
Transmittal 10837	Date: June 11, 2021		
	Change Request 12290		

SUBJECT: National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs)

I. SUMMARY OF CHANGES: The purpose of this Change Request is to inform contractors that effective December 1, 2020, CMS covers Ventricular Assist Devices (VADs) under certain conditions and criteria.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: December 1, 2020

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 27, 2021

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated) R=REVISED, N=NEW, D=DELETED-*Only One Per Row*.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/20/9/ Artificial Hearts and Related Devices
R	1/20/9/1/Ventricular Assist Devices (VADs)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

SUBJECT: National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs)

EFFECTIVE DATE: December 1, 2020

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 27, 2021

I. GENERAL INFORMATION

A. Background: Ventricular assist devices (VADs) or left ventricular assist devices (LVADs) are mechanical blood pumps that are surgically attached to one or both intact ventricles of a damaged or weakened native heart to assist in pumping blood. The heart remains intact with VADs with the possibility for the native heart to recover and for removal of the device. Patients who may be candidates for LVAD implant undergo extensive clinical testing to ensure an adequate severity of heart failure but acceptable severity of comorbidities.

Section 20.9.1 of the Medicare National Coverage Determinations (NCD) Manual establishes conditions of coverage for VADs. In 1993, the Centers for Medicare & Medicaid Services (CMS) first issued an NCD providing limited coverage of VADs and the policy has been expanded over the years. CMS last reconsidered this NCD in 2013.

B. Policy: Advanced Heart Failure

Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) $\leq 25\%$; and
- Are inotrope dependent OR

have a Cardiac Index (CI) [2.2 L/min/m2, while not on inotropes, and also meet one of the following:

- Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
- Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

The process for organizations to apply for CMS approval to be designated as a credentialing organization for VAD facilities is posted on our web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Re	espo	nsil	bilit	y				
			A/B	}	D	,	Sha	red-		Other
		N	MA(\mathbb{C}	M		Sys	tem		
					Е	M	aint	aine	ers	
		A	В	Н		F	M	V	C	
				Н	M	I	C	M	W	
				Н	A	S	S	S	F	
					С	S				
12290 -	Effective for dates of services on or after December 1,	X	X							
03.1	2020 contractors shall be aware that CMS covers									
	VADS under the conditions and criteria outlined in									
	NCD Manual Section 20.9.1. Please refer to the									
	Claims Process Manual Section 32, Chapter 320 for									
	claims processing instructions.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsib	ility	
			A/B MA(D M E	C E D
		A	В	H H H	M A C	Ι
12290 - 03.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the	X	X			

Number	Requirement		spo	nsib	ility	7
			A/B		D	C
		I	MA(\mathbb{C}	M	E
					Е	D
		Α	В	Н		I
				Н	M	
				Н	A	
					C	
	Medicare program correctly. Subscribe to the "MLN Matters" listsery to get					
	article release notifications, or review them in the MLN Connects weekly					
	newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage and Analysis), Rachel Kotanak, 410-786-8564 or Rachel.Kotonak@cms.hhs.gov (Coverage and Analysis), Thomas Dorsey, 410-785-7434 or ThomasDo.rsey@cms.hhs.gov (Professional Billing), Yvonne Young, 410-786-1886 or Yvonne.Young@cms.hhs.gov (Institutional Billing), Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

```
20.9 – Artificial Hearts and Related Devices (Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)
```

Effective December 1, 2020, Artificial Hearts has been removed from the NCD Manual.

20.9.1 – Ventricular Assist Devices (VADs) (Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

A. General

A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

- 2. Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:
 - Have New York Heart Association (NYHA) Class IV heart failure; and
 - Have a left ventricular ejection fraction (LVEF) $\leq 25\%$; and
 - Are inotrope dependent
 OR
 have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
 - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
 - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

• At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.

- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by CMS. The process for organizations to apply for CMS approval to be designated as a credentialing organization for LVAD facilities is posted on our web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/VAD-Destination-Therapy-Facilities.html

C. Nationally Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

320 - Artificial Hearts and Related Devices

(Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective for claims with dates of service on or after December 1, 2020, as a result of a reconsideration of National Coverage Determination (NCD) 20.9 of the Medicare NCD Manual, coverage determinations for artificial hearts and related devices shall be made by the Medicare Administrative Contractors.

320.3 – Ventricular Assist Devices (VADs)

(Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Medicare may cover a Ventricular Assist Device (VAD). A VAD is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed. Refer to the *Internet Only Manual Publication* 100-03, *National Coverage Determination (NCD) Manual, section 20.9.1*, for coverage criteria.

320.3.1 – Post-Cardiotomy

(Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

320.3.2 – VADs for Short-term or Long-term Mechanical Circulatory Support (Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective for claims with dates of service on or after December 1, 2020, Left ventricular assist devices (LVADs) are covered if they are FDA-approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet specific clinical criteria outlined in NCD 20.9.1.

320.3.3 – Other

(Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual.

Claims Coding

Appropriate ICD-10 diagnosis and procedure codes are included below:

ICD-10	Definition
Diagnosis Code	
109.81	Rheumatic heart failure
111.0	Hypertensive heart disease with heart failure

l13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease,
115.0	or unspecified chronic kidney disease
113.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end
120.0	stage renal disease
120.0	Unstable angina
121.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
	ST elevation (STEMI) myocardial infarction involving left
121.02	anterior descending coronary artery
	ST elevation (STEMI) myocardial infarction involving
121.09	other coronary artery of anterior wall
	ST elevation (STEMI) myocardial infarction involving
121.11	right coronary artery
	ST elevation (STEMI) myocardial infarction involving
121.19	other coronary artery of inferior wall
	ST elevation (STEMI) myocardial infarction involving left
121.21	circumflex coronary artery
	ST elevation (STEMI) myocardial infarction involving
121.29	other sites
	ST elevation (STEMI) myocardial infarction of
121.3	unspecified site
121.4	Non-ST elevation (NSTEMI) myocardial infarction
	Subsequent ST elevation (STEMI) myocardial infarction
122.0	of anterior wall
	Subsequent ST elevation (STEMI) myocardial infarction
122.1	of inferior wall

	Subsequent non-ST elevation (NSTEMI) myocardial
122.2	infarction
	Subsequent ST elevation (STEMI) myocardial infarction
122.8	of other sites
122.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
	Acute coronary thrombosis not resulting in myocardial
124.0	infarction
124.1	Dressler's syndrome
124.8	Other forms of acute ischemic heart disease
124.9	Acute ischemic heart disease, unspecified
	Atherosclerotic heart disease of native coronary artery
125.10	without angina pectoris
	Atherosclerotic heart disease of native coronary artery
125.110	with unstable angina pectoris
	Atherosclerotic heart disease of native coronary artery
125.111	with angina pectoris with documented spasm
	<u> </u>

125.710	graft(s) with unstable angina pectoris
	Atherosclerosis of autologous vein coronary artery bypass
125.709	unspecified, with unspecified angina pectoris
	Atherosclerosis of coronary artery bypass graft(s),
125.708	unspecified, with other forms of angina pectoris
	Atherosclerosis of coronary artery bypass graft(s),
125.701	unspecified, with angina pectoris with documented spasm
	Atherosclerosis of coronary artery bypass graft(s),
125.700	unspecified, with unstable angina pectoris
	Atherosclerosis of coronary artery bypass graft(s),
125.6	Silent myocardial ischemia
125.5	Ischemic cardiomyopathy
125.119	with unspecified angina pectoris
	Atherosclerotic heart disease of native coronary artery
125.118	with other forms of angina pectoris
	Atherosclerotic heart disease of native coronary artery

	Atherosclerosis of autologous vein coronary artery bypass
125.711	graft(s) with angina pectoris with documented spasm
	Atherosclerosis of autologous vein coronary artery bypass
125.718	graft(s) with other forms of angina pectoris
	Atherosclerosis of autologous vein coronary artery bypass
125.719	graft(s) with unspecified angina pectoris
	Atherosclerosis of autologous artery coronary artery
125.720	bypass graft(s) with unstable angina pectoris
	Atherosclerosis of autologous artery coronary artery
125.721	bypass graft(s) with angina pectoris with documented spasm
	Atherosclerosis of autologous artery coronary artery
125.728	bypass graft(s) with other forms of angina pectoris
	Atherosclerosis of autologous artery coronary artery
125.729	bypass graft(s) with unspecified angina pectoris
	Atherosclerosis of nonautologous biological coronary artery
125.730	bypass graft(s) with unstable angina pectoris
	Atherosclerosis of nonautologous biological coronary artery
125.731	bypass graft(s) with angina pectoris with
	documented spasm
	Atherosclerosis of nonautologous biological coronary
125.738	artery bypass graft(s) with other forms of angina pectoris
	Atherosclerosis of nonautologous biological coronary
125.739	artery bypass graft(s) with unspecified angina pectoris
	Atherosclerosis of native coronary artery of transplanted
125.750	heart with unstable angina
	Atherosclerosis of native coronary artery of transplanted
125.751	heart with angina pectoris with documented spasm
	Atherosclerosis of native coronary artery of transplanted
125.758	heart with other forms of angina pectoris

	Atherosclerosis of native coronary artery of transplanted
125.759	heart with unspecified angina pectoris
	Atherosclerosis of bypass graft of coronary artery of
125.760	transplanted heart with unstable angina

	Atherosclerosis of bypass graft of coronary artery of transplanted
125.761	heart with angina pectoris with documented
	spasm
	Atherosclerosis of bypass graft of coronary artery of transplanted
125.768	heart with other forms of angina pectoris
	Atherosclerosis of bypass graft of coronary artery of
125.769	transplanted heart with unspecified angina pectoris
	Atherosclerosis of other coronary artery bypass graft(s)
125.790	with unstable angina pectoris
	Atherosclerosis of other coronary artery bypass graft(s)
125.791	with angina pectoris with documented spasm
	Atherosclerosis of other coronary artery bypass graft(s)
125.798	with other forms of angina pectoris
	Atherosclerosis of other coronary artery bypass graft(s)
125.799	with unspecified angina pectoris
	Atherosclerosis of coronary artery bypass graft(s) without
125.810	angina pectoris
	Atherosclerosis of native coronary artery of transplanted
125.811	heart without angina pectoris
	Atherosclerosis of bypass graft of coronary artery of
125.812	transplanted heart without angina pectoris
125.89	Other forms of chronic ischemic heart disease
125.9	Chronic ischemic heart disease, unspecified
134.0	Nonrheumatic mitral (valve) insufficiency
134.1	Nonrheumatic mitral (valve) prolapse
134.2	Nonrheumatic mitral (valve) stenosis
134.8	Other nonrheumatic mitral valve disorders
134.9	Nonrheumatic mitral valve disorder, unspecified
135.0	Nonrheumatic aortic (valve) stenosis
135.1	Nonrheumatic aortic (valve) insufficiency
135.2	Nonrheumatic aortic (valve) stenosis with insufficiency
135.8	Other nonrheumatic aortic valve disorders
135.9	Nonrheumatic aortic valve disorder, unspecified
136.0	Nonrheumatic tricuspid (valve) stenosis
136.1	Nonrheumatic tricuspid (valve) insufficiency

136.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
136.8	Other nonrheumatic tricuspid valve disorders
136.9	Nonrheumatic tricuspid valve disorder, unspecified
137.0	Nonrheumatic pulmonary valve stenosis
137.1	Nonrheumatic pulmonary valve insufficiency

Nonrheumatic pulmonary valve stenosis with	
insufficiency	
Other nonrheumatic pulmonary valve disorders	
Nonrheumatic pulmonary valve disorder, unspecified	
Endocarditis, valve unspecified	
Endocarditis and heart valve disorders in diseases	
classified elsewhere	
Dilated cardiomyopathy	
Other hypertrophic cardiomyopathy	
Endomyocardial (eosinophilic) disease	
Endocardial fibroelastosis	
Other restrictive cardiomyopathy	
Alcoholic cardiomyopathy	
Cardiomyopathy due to drug and external agent	
Other cardiomyopathies	
Cardiomyopathy, unspecified	
Cardiomyopathy in diseases classified elsewhere	
Cardiac arrest due to underlying cardiac condition	
Cardiac arrest due to other underlying condition	
Cardiac arrest, cause unspecified	
Re-entry ventricular arrhythmia	
Supraventricular tachycardia	
Ventricular tachycardia	
Paroxysmal tachycardia, unspecified	
Atrial fibrillation	
Longstanding persistent atrial fibrillation	
Other persistent atrial fibrillation	
Ventricular fibrillation	

149.02	Ventricular flutter
149.1	Atrial premature depolarization
149.2	Junctional premature depolarization
149.3	Ventricular premature depolarization
149.40	Unspecified premature depolarization
149.49	Other premature depolarization
149.5	Sick sinus syndrome
149.8	Other specified cardiac arrhythmias
149.9	Cardiac arrhythmia, unspecified
150.1	Left ventricular failure
150.20	Unspecified systolic (congestive) heart failure
150.21	Acute systolic (congestive) heart failure
150.22	Chronic systolic (congestive) heart failure
150.23	Acute on chronic systolic (congestive) heart failure
150.30	Unspecified diastolic (congestive) heart failure
150.31	Acute diastolic (congestive) heart failure
150.32	Chronic diastolic (congestive) heart failure
150.33	Acute on chronic diastolic (congestive) heart failure

г

	Unspecified combined systolic (congestive) and diastolic
150.40	(congestive) heart failure
	Acute combined systolic (congestive) and diastolic
150.41	(congestive) heart failure
	Chronic combined systolic (congestive) and diastolic
150.42	(congestive) heart failure
	Acute on chronic combined systolic (congestive) and diastolic
150.43	(congestive) heart failure
150.84	End-stage heart failure
150.9	Heart failure, unspecified
151.4	Myocarditis, unspecified
151.9	Heart disease, unspecified
152	Other heart disorders in diseases classified elsewhere
197.0	Postcardiotomy syndrome
	Postprocedural cardiac insufficiency following cardiac

197.110	surgery
	Postprocedural cardiac insufficiency following other
197.111	surgery
197.120	Postprocedural cardiac arrest following cardiac surgery
197.121	Postprocedural cardiac arrest following other surgery
197.130	Postprocedural heart failure following cardiac surgery
197.131	Postprocedural heart failure following other surgery
	Other postprocedural cardiac functional disturbances
197.190	following cardiac surgery
	Other postprocedural cardiac functional disturbances
197.191	following other surgery
197.710	Intraoperative cardiac arrest during cardiac surgery
197.711	Intraoperative cardiac arrest during other surgery
	Other intraoperative cardiac functional disturbances
197.790	during cardiac surgery
	Other intraoperative cardiac functional disturbances
197.791	during other surgery
	Other intraoperative complications of the circulatory
197.88	system, not elsewhere classified
197.89	Other postprocedural complications and disorders of the circulatory system, not elsewhere classified
M32.11	Endocarditis in systemic lupus erythematosus
R00.1	Bradycardia, unspecified
R57.0	Cardiogenic shock
	Breakdown (mechanical) of biological heart valve graft,
T82.221A	initial encounter
	Displacement of biological heart valve graft, initial
T82.222A	encounter
T82.223A	Leakage of biological heart valve graft, initial encounter
	•
	Other mechanical complication of biological heart valve

	Other mechanical complication of biological heart valve
T82.228A	graft, initial encounter
	Breakdown (mechanical) of artificial heart, initial
T82.512A	encounter

	Breakdown (mechanical) of infusion catheter, initial	
T82.514A	encounter	
T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter	
102.310/1		
T82.522A	Displacement of artificial heart, initial encounter	
	Displacement of other cardiac and vascular devices and	
T82.528A	implants, initial encounter	
	Displacement of unspecified cardiac and vascular devices	
T82.529A	and implants, initial encounter	
T82.532A	Leakage of artificial heart, initial encounter	
	Leakage of other cardiac and vascular devices and	
T82.538A	implants, initial encounter	
	Other made print and intimation of artificial boost initial	
T82.592A	Other mechanical complication of artificial heart, initial encounter	
T82.598A	Other mechanical complication of other cardiac and vascular devices and implants, initial encounter	
102.33071	vascalar devices and implants, initial encounter	
T86.20	Unspecified complication of heart transplant	
T86.21	Heart transplant rejection	
T86.22	Heart transplant failure	
T86.23	Heart transplant infection	
T86.290	Cardiac allograft vasculopathy	
T86.298	Other complications of heart transplant	
T86.30	Unspecified complication of heart-lung transplant	
T86.31	Heart-lung transplant rejection	
T86.32	Heart-lung transplant failure	
T86.33	Heart-lung transplant infection	
T86.39	Other complications of heart-lung transplant	

Z48.21	Encounter for aftercare following heart transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z94.1	Heart transplant status
Z94.3	Heart and lungs transplant status

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a) (1) (A) of the Social Security Act for VADs in these situations will be made by local Medicare Administrative Contractors (MACs) within their respective jurisdictions.

320.3.4— Replacement Accessories and Supplies for External VADs or Any VAD

(Rev. 10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

Effective April 1, 2013, claims for replacement of accessories and supplies for VADs implanted in patients who were not eligible for coverage under Medicare Part A or had other insurance that paid for the device and hospital stay at the time that the device was implanted, but are now eligible for coverage of the replacement supplies and accessories under Part B, should be submitted using HCPCS code Q0509. Those claims will be manually reviewed.

In rare instances it may be appropriate to pay for replacement of supplies and accessories for external VADs used by patient who are discharged from the hospital. In addition, in some rare instances, it may be necessary for a patient to have an emergency back-up controller for an external VAD. Coverage of these items is at the discretion of the contractor. Claims for replacement of supplies and accessories used with an external VAD that are furnished by suppliers should be billed to the Part B MACs. Claims for replacement of supplies and accessories used with an external VAD that are furnished by hospitals and other providers should be billed to the Part AMACs. Effective April 1, 2013, these items should be billed using code Q0507 so that the claims can be manually reviewed.

Claims for replacement supplies or accessories used with VADs that do not have specific HCPCS codes and do not meet the criteria of codes Q0507 and Q0509 should be billed using code Q0508.

Claims Coding

HCPCS	Definition	Effective Date
Q0507	Miscellaneous Supply Or Accessory For Use With An External Ventricular Assist Device	April 1, 2013
Q0508	Miscellaneous Supply or Accessory For Use With An Implanted Ventricular Assist Device	April 1, 2013
Q0509	Miscellaneous Supply Or Accessory For Use With Any Implanted Ventricular Assist Device For Which Payment Was Not Made Under Medicare Part A	April 1, 2013

Q0480:Driver for use with pneumatic ventricular assist device, replacement only

Q0481:Microprocessor control unit for use with electric ventricular assist device, replacement only

Q0482:Microprocessor control unit for use with electric/pneumatic combination ventricular assist device, replacement only

Q0483:Monitor/display module for use with electric ventricular assist device, replacement only

Q0484:Monitor/display module for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0485:Monitor control cable for use with electric ventricular assist device, replacement only

Q0486:Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only

Q0487:Leads (pneumatic/electrical) for use with any type electric/pneumatic ventricular assist device, replacement only

Q0488:Power pack base for use with electric ventricular assist device, replacement only

Q0489:Power pack base for use with electric/pneumatic ventricular assist device, replacement only

Q0490:Emergency power source for use with electric ventricular assist device, replacement only

Q0491:Emergency power source for use with electric/pneumatic ventricular assist device, replacement only

Q0492:Emergency power supply cable for use with electric ventricular assist device, replacement only

Q0493:Emergency power supply cable for use with electric/pneumatic ventricular assist device, replacement only

Q0494:Emergency hand pump for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0495:Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0496:Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0497:Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0498:Holster for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0499:Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only

Q0500:Filters for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0501:Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only

Q0502:Mobility cart for pneumatic ventricular assist device, replacement only

Q0503:Battery for pneumatic ventricular assist device, replacement only, each

Q0504:Power adapter for pneumatic ventricular assist device, replacement only, vehicle type

Q0506:Battery, lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only

NOTE: When determined to be medically necessary, dressings used with VADs are covered under the prosthetic device benefit as a supply necessary for the effective use of the VAD/prosthetic device. Claims for dressings necessary for the effective use of a VAD should be billed using the appropriate miscellaneous VAD supply code, depending upon whether the patient was eligible for coverage under Medicare Part A at the time that the VAD was implanted. The claims processing jurisdiction for dressings used with VADs is identical to that of other VAD replacement supplies and accessories and does not fall under Durable Medical Equipment MAC jurisdiction.

R0037_CP2

NCO LIMA NCO LIMA ICO 10 CM	
ICD-10 CM	Mis New yes softendations and Gudence Gudence Manuals Marchaelchol 123: 1 Fart and
ICD-10 CM	On the control of the
	ICD-10 DX Description
	CMX reserves the right to add or remove codes associated with its NCOs in order to implement those
	SCDs to the result efficient manner within the continues of the sortion.
l	As this parity indicates, included AM MACs within their respective jurisdictions have the discretion
l	Social Security Act. Therefore, A/S MACs may have additional covered diagnosis codes in their
	Individual pullides where contactor discretion is appropriate.
111.0	Manuals had bless with test blue
	Hyperbesche heart and chrosic kidney dawase with heart fature and stage 1 through stage 4 choices kidney
	Pyperbescie heart and chrosis kidney disease with heart failure and with stage 5 chrosis kidney disease, or
13.2	State real disease
21 21	ST elegation (STEM) revocable infantion treatment of main coronary afters
21.02 21.09	3.7 elegation (2.79M) revocabilit inflaction treatment left proteon decomples company afters 3.7 elegation (2.79M) revocabilit inflaction treatment other commany afters of archetic wall
3111	ET etration (ETEM) evocastial infantion tradem until conney aftery
21.21	3T virgation (3TBM) revocastial infantion treatment of circumfer consears afters
21.29	3.7 elegiber (2.78 M) myocastid intention meters other sites. 3.7 elegiber (2.78 M) myocastid intention of propertied site.
21.6	Non-ET structure (NETERAL recognition infection)
32 1	Euloreaumi ST elevation CEBMS environable infection of infector wall
****	Published NY sheets - NY MAY may safer sheets of other char
24.0	Statement ST abouton STMMS concepted shortes of conscillations Acute conserve Statement and secretary to concepted shortes
26.1	Crescie's syndrome
26.8	Other Sames of acute inchemic head disease Acute hichemic head disease, unspecified
09.10 19.10	Alteroschendic bead disease of notice common arters without arrang pecturis.
58 TE	Edwoodentic least disease of rather commit with annius section with discurrented associated
20 179	Afterior lends head disease of online consons when with other bone of norms section. Afterior lends head disease of notice consons after with unuseded anoine periods.
20.5	bulents sedimosally
20.70	Silved resourcing technical Althropolymous of consists when broass souths; unspecified with unstable analisa sections
20.708	Atherophenois of coronary attent bypass profits I unspecified with other forms of anging pectoris
24 700 20 710	numerousmous of common after broass sodies, unspecified with unspecified arrang sections. Aftersopherous of authorized with common after broass sodies with unspecified proma sections.
OR TH	Electrolates of address and contact after boson and the set and a
20.73	Effectively of exhibition will common when because within with writin earlies with the control of Effectively of exhibitions will colorary after bycass walls) with other bring of engine section.
20.739	Effectivelymous of autologics was connect after broads staffed with undersided anning sections. Effectivelymous of autologics after connect after broads public with underly anning environs.
10 FM	e-manufacture of exhibitions after content when houses coefficients exists section with documented or differentiations of exhibitions after content when houses coefficiently often have of exhibit sections
25.729 29.730	Effective leaves of authorized after contrary after broads profit with presented analog section. Effective leaves of republishment belonged contrary after broads profit; with profit to contrary and contrary after broads profit with profit and contrary after broads profit and contrary after broad
	Afteroscience of nanadiological biological coronary aftery bypecs graff(s) with angine pecials with documents
29,721	SEASON .
09 TM	Afternologics of connections as industrial colonies after boson staffe; with other boson of angine section
24 728 28 730	numerousmous of nonadelessors bedested coronary after broass seaffer with unused field another sections. Althorophysics of native coronary afters of beautisated head with unstable around
20 701 20 707	Effectively of rathe conservation of bossisted had after acting sectors with documented scans. Siterioralization of rathe conservation of basedaying had with their times of events or
09.70P	Afterioralismois of native conserv active of barealarded head with unsampled anima declaris
OR 760	Atherospherous of business and of common artery of transplanted head with undafter anima
1	Alternationals of bypass grill of coronary artery of transplanted head with angine pectors with documented
20 7KI 20 7KF	Special Communication of Special Conference of the Special Conference of Special Confere
25.70	Edward reads of books and of comerciating of breaders that all properties aring patients
20.70	Etherophropis of other corporary after books sudfix) with another sections with documented spaces
26.79E	Attenuationals of other constant after broats staffic with other terms of anomal embods. Attenuationals of other constant after broats staffic with unswelfed anomal sectors.
W-8-W	Electrolassic of contain what forest unified without souther seriors
20.817	Atheroschemics of native commany artery of homestanded head without anothing pectorie. Atheroschemics of business until of commany artery of transacterised head without anothin sentimes.
39.89	Alteriorate of broass and of constant arters of translated heat without areins sections. Clien fames of divorse harberton least disease.
26.0	Planto tribute had dealer contactful Strebeunds what had insufaces
26.1 26.2	Somheumatic mitted trather andrates Somheumatic mitted trather stemanic
20.5	Other condequatio minist side disorders
34.8 38.0	Numbermatic withol safe disorder, unspecified. Numbermatic audio rudes element.
i	Somewhats auto reserve resilianes
20.5	Other nontheumatic aurits wider disorders
20.9	Someonatic acts whe decide, unspected Someonatic Soussel father stenosis
31	Standardisch Stockald Sather Insufficiency Standardisch Stockald Sather Standard with the Missaco
3.0	Other nontheumatic tricusard with discretes
m 1	surrounum museum wordstatter unsended Studentials indentials and observe
371	Stonheumatic submonary valve Insufficiency
27.8	Other nontheumatic outnorsary safer doubles
2	Enducation was unswided
39 60.0	Endocardits and head value disorders in diseases classified storuferse District cardiomycologics
-	Pillar banadischer vandenschafte.
91	Endocarda Stransaciona
95	Other methodise cardiomyssolity Rhisholis cardiomyssolity
101	Continuouslity due to drug and external assets Other continuouslities
4.0	Cadomosally, usuaded
01.2	Cardiac area' day lo underlong cardiac prodition
00.7	Cardias arred due to other underlying condition Cardias arred, cause unspecified
er o	Reads with the ship and
67.2	Verbicular bacherianda
19/ B	resorme serviceda unascided son formano
d# 11	Considerating president atted floritation
10 TO	
68:02 68:1	Definide Belleton Definide Baller Ande semante desiration
#32 #1 #2	Terdinada Bellation Ferdinada Editation Ferdinada Edit Ferdinada E
80 mm	Terbinak Beliatus Federak Marie Aliat semalan deslarkishin Antimu semalan deslarkishin Federak semalan deslarkishin Federak semalan deslarkishin Federak semalan deslarkishin
80 81 82 83	Protection furnitum Translate Inform Translate Inform Annual Information Inform Annual Information Inform Annual Information Information Translate amounts and descriptions Translate amounts or descriptions Translate Information Information Translate Information T
80 81 82 83 83 83 83	Translation designation Translation designation Anthread constant designation Anthread con
8.0 8.1 8.2 8.3 8.1 8.1 8.1 8.1	Transparent Halliams Transparent John Transpar
880 81 82 83 83 83 81 81 81 80	Todasiah Bindiana Todasiah Bindiana Johanna antanata mandatanat Johanna antanata mandatanat Johanna antanata mandatanatan Johanna antanata mandatanatan Johanna antanatanatanatanatanatanatanatanat
#32 #3 #3 #4 #4 #4 #4 #4 #4 #4 #4 #4 #4 #4 #4 #4	Comment Delication And Comment Delication And Comment Delication Comment Delication And Comment De
# 52 # 1 # 3 # 3 # 4 # 3 # 3 # 3 # 3 # 3 # 3 # 3 # 3 # 3 # 3	Commande Marine And Commande
# 52 # 1 # 2 # 3 # 3 # 4 # 3 # 3 # 3 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5	Colonia Monte. Managara Manag
# 102 # 1 # 2 # 3 # 4	Content Monte. All Annual Association of Content Association of Con
# 92 # 1 # 2 # 3 # 3 # 4 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5 # 5	Content Montes Option Content
# 102 # 12 # 12 # 13 # 13 # 14 # 15 # 15 # 15 # 15 # 15 # 15 # 15 # 15	Annua Maria. The state of the
##2 ##3 ##3 ##3 ##3 ##4 ##3 ##3 ##3 ##3 ##3	And the best of the second of
施力 施力 施力 施力 通力 通点 通点 通点 通点 通点 通点 通点 通点 通点 通点	And the second s
	Annual Maria Carlo
##27 ##3 ##3 ##3 ##4 ##4 ##4 ##4 ##4 ##4 ##4	Annual Marian Carlos Ca
## 22 ## 22	And the second s
### 12	
## 1	And the second s
### 1	And the second s
20 22 22 22 23 24 25 25 25 25 25 25 25 25 25 25 25 25 25	
20 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
2002 2012 2013 2014 2015 2015 2016 2016 2017 2017 2017 2017 2017 2017 2017 2017	
20 22 22 22 22 22 22 22 22 22 22 22 22 2	Andread Marie Committee Co
200 (20) 200	
### 12	
200 (200) 200 (200)	
200 200 200 200 200 200 200 200 200 200	
2012 20	
20 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
2012 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
20 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
2012 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
### 12 PA	
2012 20	
### 12	
### 12	
201 201	
22 2 2 2 2 2 2 2 2 2	
201 201	
### 12	

Pay 1d

R10837_CP2 ICD Procedures

NCD:	20.9.1
NCD Title:	Ventricular Assist Devices
IOM:	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1 Part1.pdf
NCD Link	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ver=1
ICD-10 PCS	ICD-10 PCS Description
	CMS reserves the right to add or remove codes associated with its NCDs in order to implement
	those NCDs in the most efficient manner within the confines of the policy.
	VADs (NCD 20.9.1)
02HA0QZ	Insertion of Implantable Heart Assist System into Heart, Open Approach
02PA0QZ	Removal of Implantable Heart Assist System from Heart, Open Approach
02WA0QZ	Revision of Implantable Heart Assist System in Heart, Open Approach

R10837_CP2 Rule Description

NCD	: 20.9.1									
NCD Title	: Ventricular Assist Devices (CR8803, CR9087, CR9252, CR10318, CR11491, CR12290)									
IOM	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1	Part1.pdf								
NCD Link http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ver=1										
Part A	Rule Description Part A A/MACs: Effective DOS 12/1/20, VADs was reconsidered. CMS updated coverage	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
	criteria for tx of advanced heart failure. Therapeutic intent was removed. Patient selection criteria was revised. Facility criteria remains unchanged. No changes to claims processing edits.									
Part A	A/MACs: Effective DOS 10/18/93, VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. A/MACs: Effective DOS 1/22/96, VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the criteria mentioned in NCD must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant. A/MACs: Effective DOS 10/1/03 (facility criteria updated 10/30/13, patient selection criteria updated 11/9/10), VADs as destination therapy using the criteria described in NCD 20.9.1 are covered. NOTE: There might be other uses of VADs and Related Supplies besides those mentioned in NCD.	N/A (see applicable ICD-10-PCS codes)	N/A	N/A	N/A	N/A	N/A	15.20	50	N386
Part A	A/MACs: shall reject all other indications for the use of VADs not otherwise listed as non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual. NOTE: NCD does not address coverage of VADs for right ventricular support, biventricular support, use in patients under the age of 18, or use in patients with complex congenital heart disease and that coverage for items and services under section 1862(a)(1)(A) in these situations will be made by local MACs within their respective jurisdictions.		N/A	N/A	N/A	N/A	N/A	15.20	50	N386

NCD	20.9.1									
NCD Title	Ventricular Assist Devices (CR8803, CR9087, CR9252, CR10318, CR11491, CR12290)									
IOM	http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1	Part1.pdf								
NCD Link	http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&v	<u>/er=1</u>								
Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
	B/MACs: Effective DOS 12/1/20, VADs was reconsidered. CMS updated coverage criteria for tx of advanced heart failure. Therapeutic intent was removed. Patient selection criteria was revised. Facility criteria remains unchanged. No changes to claims processing edits.									
Part B	B/MACs: Effective 10/18/93, VADs used for support of blood circulation post-cardiotomy covered only if FDA-approved for that purpose, and VADs are used according to FDA-approved labeling instructions. B/MACs: Effective 1/22/96, VADs used for bridge-to-transplant are covered only if FDA-approved for that purpose, and VADs are used according to FDA-approved labeling instructions. All criteria mentioned in NCD must be fulfilled in order for Medicare coverage to be provided for VAD used as a bridge-to-transplant. B/MACs: Effective 10/1/03 (facility criteria effective 10/1/13, patient selection criteria updated 11/9/10), VADs as destination therapy using criteria described in NCD 20.9.1 are covered. NOTE: There might be other uses of VADs and Related Supplies besides those mentioned in NCD. Please refer to CR 7888 dated 12/21/12 for further claim instructions regarding Q0508 & Q0509. B/MACs: Shall reject all other indications for the use of VADs not otherwise listed as non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual. NOTE: NCD does not address coverage of VADs for right ventricular support, biventricular support, use in patients under the age of 18, or use in patients with complex congenital heart disease and that coverage for items and services under section 1862(a)(1)(A) in these situations will be made by local MACs within their respective jurisdictions.	VADs= 33979-33980; 33982-33983 VAD related supplies= Q0480-Q0506, Q0508 & Q0509	N/A N/A	N/A	N/A	N/A	N/A N/A	15.20	50	N386 N386
	Revision History CR9252: Clarify for First Coast that MCE edits W1529-W1534 should be updated with ICI Remove ICD-10 dx NOC codes Z95.9, T82.599A, T82.594A, T82.539A, T82.534A, T82.5 CR90927: Minor formatting changes. Poleta "draft" from decument.		Palmetto							
	CR9087: Minor formatting changes. Delete "draft" from document. Remove congenital ICD-10 dx that are at contractor's discretion. New spreadsheet created based on CR8803. Contractor discretion language added to dx code tab. Remove shared system responsibility. CR10318: Add 2018 ICD-10 dx I50.84 effective 10/1/17. CR11491: End-date ICD-10 dx I48.1 effective 9/30/19. Add ICD-10 dx I48.11, I48.19 effective 10/1/19. CR12290: Spreadsheet and CPM updated to reflect reconsideration effective 12/1/20.									