

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

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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) $[\geq 2.2 \text{ L/min/m}^2$, 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	Responsibility							
		A/B MAC		D M E M A C	Shared- System Maintainers				Other
		A	B		H H H	F I S S	M C S	V M S	
12290 - 03.1	Effective for dates of services on or after December 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.	X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E M A C	C E D I	I
		A	B	H H H			
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	Responsibility				
		A/B MAC			D M E D I	C E D I
		A	B	H H H		
	Medicare program correctly. Subscribe to the “MLN Matters” listserv 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 Requirement Number	Recommendations or other supporting information:

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/MedicareApprovedFacilitie/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 Diagnosis Code	Definition
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure

I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease
I20.0	Unstable angina
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall

I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I24.0	Acute coronary thrombosis not resulting in myocardial infarction
I24.1	Dressler's syndrome
I24.8	Other forms of acute ischemic heart disease
I24.9	Acute ischemic heart disease, unspecified
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm

I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.5	Ischemic cardiomyopathy
I25.6	Silent myocardial ischemia
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris

I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris

I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina

I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.8	Other nonrheumatic mitral valve disorders
I34.9	Nonrheumatic mitral valve disorder, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8	Other nonrheumatic aortic valve disorders
I35.9	Nonrheumatic aortic valve disorder, unspecified
I36.0	Nonrheumatic tricuspid (valve) stenosis
I36.1	Nonrheumatic tricuspid (valve) insufficiency

I36.2	Nonrheumatic tricuspid (valve) stenosis with insufficiency
I36.8	Other nonrheumatic tricuspid valve disorders
I36.9	Nonrheumatic tricuspid valve disorder, unspecified
I37.0	Nonrheumatic pulmonary valve stenosis
I37.1	Nonrheumatic pulmonary valve insufficiency

I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
I37.8	Other nonrheumatic pulmonary valve disorders
I37.9	Nonrheumatic pulmonary valve disorder, unspecified
I38	Endocarditis, valve unspecified
I39	Endocarditis and heart valve disorders in diseases classified elsewhere
I42.0	Dilated cardiomyopathy
I42.2	Other hypertrophic cardiomyopathy
I42.3	Endomyocardial (eosinophilic) disease
I42.4	Endocardial fibroelastosis
I42.5	Other restrictive cardiomyopathy
I42.6	Alcoholic cardiomyopathy
I42.7	Cardiomyopathy due to drug and external agent
I42.8	Other cardiomyopathies
I42.9	Cardiomyopathy, unspecified
I43	Cardiomyopathy in diseases classified elsewhere
I46.2	Cardiac arrest due to underlying cardiac condition
I46.8	Cardiac arrest due to other underlying condition
I46.9	Cardiac arrest, cause unspecified
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I47.9	Paroxysmal tachycardia, unspecified
I48.0	Atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I49.01	Ventricular fibrillation

I49.02	Ventricular flutter
I49.1	Atrial premature depolarization
I49.2	Junctional premature depolarization
I49.3	Ventricular premature depolarization
I49.40	Unspecified premature depolarization
I49.49	Other premature depolarization
I49.5	Sick sinus syndrome
I49.8	Other specified cardiac arrhythmias
I49.9	Cardiac arrhythmia, unspecified
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure

I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.84	End-stage heart failure
I50.9	Heart failure, unspecified
I51.4	Myocarditis, unspecified
I51.9	Heart disease, unspecified
I52	Other heart disorders in diseases classified elsewhere
I97.0	Postcardiotomy syndrome
	Postprocedural cardiac insufficiency following cardiac

I97.110	surgery
I97.111	Postprocedural cardiac insufficiency following other surgery
I97.120	Postprocedural cardiac arrest following cardiac surgery
I97.121	Postprocedural cardiac arrest following other surgery
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I97.191	Other postprocedural cardiac functional disturbances following other surgery
I97.710	Intraoperative cardiac arrest during cardiac surgery
I97.711	Intraoperative cardiac arrest during other surgery
I97.790	Other intraoperative cardiac functional disturbances during cardiac surgery
I97.791	Other intraoperative cardiac functional disturbances during other surgery
I97.88	Other intraoperative complications of the circulatory system, not elsewhere classified
I97.89	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
T82.221A	Breakdown (mechanical) of biological heart valve graft, initial encounter
T82.222A	Displacement of biological heart valve graft, initial encounter
T82.223A	Leakage of biological heart valve graft, initial encounter

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

T82.514A	Breakdown (mechanical) of infusion catheter, initial encounter
T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter
T82.522A	Displacement of artificial heart, initial encounter
T82.528A	Displacement of other cardiac and vascular devices and implants, initial encounter
T82.529A	Displacement of unspecified cardiac and vascular devices and implants, initial encounter
T82.532A	Leakage of artificial heart, initial encounter
T82.538A	Leakage of other cardiac and vascular devices and implants, initial encounter
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
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.

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

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	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
	A/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.									
	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
	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&ver=1										
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
	<p>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.</p>									
Part B	<p>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.</p> <p>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.</p> <p>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.</p> <p>NOTE: There might be other uses of VADs and Related Supplies besides those mentioned in NCD.</p> <p>Please refer to CR 7888 dated 12/21/12 for further claim instructions regarding Q0508 & Q0509.</p>	<p>VADs= 33979-33980; 33982-33983 VAD related supplies= Q0480-Q0506, Q0508 & Q0509</p>	N/A	N/A	N/A	N/A	N/A	15.20	50	N386
Part B	<p>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.</p> <p>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.</p>		N/A	N/A	N/A	N/A	N/A	15.20	50	N386
Revision History CR9252: Clarify for First Coast that MCE edits W1529-W1534 should be updated with ICD-10. Remove ICD-10 dx NOC codes Z95.9, T82.599A, T82.594A, T82.539A, T82.534A, T82.524A, T82.519A per 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.										