

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 172	Date: August 29, 2014
	Change Request 8803

SUBJECT: Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy

I. SUMMARY OF CHANGES: This Change Request (CR) is effective for claims with dates of service on and after October 30, 2013; contractors shall pay claims for Ventricular Assisted Devices as destination therapy using the criteria in Pub. 100-03, chapter 1, section 20.9.1, and Pub. 100-04, Chapter 32, sec. 320.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 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: October 30, 2013

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

IMPLEMENTATION DATE: September 30, 2014

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 (Various Effective Dates Below)
N	1/20.9.1/Ventricular Assist Devices (Various Effective Dates Below)

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 obliged 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

Pub. 100-03	Transmittal: 172	Date: August 29 ,2014	Change Request: 8803
-------------	------------------	-----------------------	----------------------

SUBJECT: Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy

EFFECTIVE DATE: October 30, 2013

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

IMPLEMENTATION DATE: September 30, 2014

I. GENERAL INFORMATION

A. Background: Medicare covers ventricular assist devices (VADs) for three general indications: postcardiotomy, bridge- to- transplantation (BTT) and destination therapy (DT). Postcardiotomy refers to the placement of VADs following open-heart surgery. Coverage for BTT is restricted to patients listed for heart transplantation. Coverage for DT is restricted to patients who are not candidates for heart transplantation, require mechanical cardiac support, and who meet specific clinical criteria. In addition, VADs implanted as DT are only covered when implanted in a facility that is approved by CMS to provide this procedure.

CMS is modifying the criteria for coverage of VADs as BTT and is modifying the facility criteria for coverage as DT as stated in the policy section below.

B. Policy:

Effective for claims with dates of service on and after October 30, 2013, CMS has determined that the evidence is adequate to conclude that VAD implantation is reasonable and necessary with the following modifications to our current policy:

- VADs for BTT: CMS clearly identifies that the patient must be active on the waitlist maintained by the Organ Procurement and Transplantation Network and remove the general time requirement that patients receive a transplant as soon as medically reasonable.
- VADs for DT: CMS expands the credentialing requirement to allow credentialing by other organizations approved by Medicare and include requirements for a multidisciplinary team. CMS removes mandatory participation in the INTERMACS registry, but encourages facilities to track patient outcomes.
- CMS states that this policy 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 Medicare Administrative Contractors (MACs) within their respective jurisdictions.
- CMS renumbers the VAD-related policies into a sub-section of section 20.9 (Artificial Hearts and Related Devices) of the NCD Manual. The sub-section (20.9.1) will be titled Ventricular Assist Devices.

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	C W F	
8803 - 03.1	Effective for claims with dates of service on and after October 30, 2013, contractors shall pay claims for VADs as destination therapy using the criteria in Pub. 100-03, part 1, section 20.9.1, and Pub. 100-04, Chapter 32, sec. 320.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
8803 - 03.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

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): Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage) , Roya Lotfi, 410-786-4072 or Roya.Lotfi@cms.hhs.gov (Coverage) , Wendy Knarr, 410-786-0843 or wendy.knarr@cms.hhs.gov (Supplier Claims Processing) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Fred Rooke, 404-562-7205 or Fred.Rooke@cms.hhs.gov (Institutional Claims Processing)

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 (Various Effective Dates Below)

(Rev.172, Issued: 08-29-14, Effective:10-30-13, Implementation:09- 30-14)

A. General

An artificial heart is a biventricular replacement device which requires removal of a substantial part of the native heart, including both ventricles. Removal of this device is not compatible with life, unless the patient has a heart transplant.

B. Nationally Covered Indications

1. *Bridge-to-transplant (BTT)* (effective for services performed on or after May 1, 2008)

An artificial heart for bridge-to-transplantation (*BTT*) is covered when performed under coverage with evidence development (CED) when a clinical study meets all of the criteria listed below. The clinical study must address at least one of the following questions:

- *Were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes?*
- *What will be the average time to device failure when the device is made available to larger numbers of patients?*
- *Do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more widespread use?*

The clinical study must meet all of the criteria stated in Section D of this policy. The above information should be mailed to: Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services (*CMS*), Re: Artificial Heart, Mailstop S3-02-01, 7500 Security Blvd, Baltimore, MD 21244-1850.

Clinical studies that are determined by CMS to meet the above requirements will be listed on the CMS Web site at: <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html>.

2. *Destination therapy (DT)* (effective for services performed on or after May 1, 2008)

An artificial heart for destination therapy (*DT*) is covered when performed under CED when a clinical study meets all of the criteria listed below. The clinical study must address at least one of the following questions:

- *Were there unique circumstances such as expertise available in a particular facility or an unusual combination of conditions in particular patients that affected their outcomes?*
- *What will be the average time to device failure when the device is made available to larger numbers of patients?*
- *Do results adequately give a reasonable indication of the full range of outcomes (both positive and negative) that might be expected from more widespread use?*

The clinical study must meet all of the criteria stated in Section D of *this policy*. The above information should be mailed to: Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services, Re: Artificial Heart, Mailstop S3-02-01, 7500 Security Blvd, Baltimore, MD 21244-1850.

Clinical studies that are determined by CMS to meet the above requirements will be listed on the CMS Web site at: <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html>.

C. Nationally Non-Covered Indications

All other indications for the use of artificial hearts 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

Clinical study criteria:

- The study must be reviewed and approved by the *Food and Drug Administration (FDA)*.
- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- The research study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated it also must be in compliance with 21 CFR Parts 50 and 56.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for *CED*.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- The clinical research study is registered on the www.ClinicalTrials.gov Web site by the principal sponsor/investigator as demonstrated by having a [ClinicalTrials.gov](http://www.ClinicalTrials.gov) *Identifier*.
- The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (ICMJE) (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally under-represented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of under-represented populations, the protocol must discuss why these criteria are necessary.
- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator of an artificial heart clinical study seeking Medicare payment should submit the following documentation to **CMS** and should expect to be notified when the CMS review is complete:

- Complete study protocol (must be dated or identified with a version number);
- Protocol summary;
- Statement that the submitted protocol version has been agreed upon by the FDA;
- Statement that the above study standards are met;
- Statement that the study addresses at least one of the above questions related to artificial hearts;
- Complete contact information (phone number, email address, and mailing address); and,
- Clinicaltrials.gov *Identifier*.

20.9.1 - Ventricular Assist Devices (Various Effective Dates Below)

Rev.172, Issued: 08-29-14, Effective: 10-30-13, Implementation: 09-30-14)

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.

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. Bridge-to-Transplant (effective for services performed on or after January 22, 1996)

The 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 FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:

- *The patient is approved for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.*
- *The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved transplant center under which the patient is listed prior to implantation of the VAD.*

3. Destination Therapy (DT) (effective for services performed on or after October 1, 2003)

Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.

Patient Selection (effective November 9, 2010):

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:

- *Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,*
- *Have a left ventricular ejection fraction (LVEF) <25%; and,*
- *Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.*

Facility Criteria (effective October 30, 2013):

Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A) of the Social Security Act (the Act):

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the 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 shared decision making and to provide appropriate informed consent. 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 VADs as BTT or DT 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 heart transplant.*
- *A VAD program coordinator.*
- *A social worker.*
- *A palliative care specialist.*

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

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.