CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 129	Date: December 8, 2010
	Change Request 7220

Transmittal 128, dated November 19, 2010, is being rescinded and replaced with Transmittal 129. The only change is in the Summary of Changes, the date of November 19, 2010, was incorrect, the correct date is November 9, 2010. Transmittal 129, issued December 8, 2010 is being re-issued to change the implementation date from December 9, 2010 to January 6, 2011. It was erroneously changed to December 9, 2010 and should have remained as January 6, 2011. The transmittal number, date issued and all other material remain the same.

SUBJECT: Ventricular Assist Devices (VAD) as Destination Therapy

I. SUMMARY OF CHANGES: Effective for claims with dates of service on or after November 9, 2010, CMS has determined that the evidence is adequate to conclude that VAD implantation as destination therapy improves health outcomes and is reasonable and necessary when the device has received FDA approval for a destination therapy indication and only for patients with NYHA Class IV end-stage ventricular heart failure who are not candidates for heart transplant and who meet all specific conditions.

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)(

EFFECTIVE DATE: November 9, 2010
IMPLEMENTATION DATE: January 6, 2011

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/20.9/Artificial Hearts and Related Devices (Various Effective Dates Below)

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 129	Date: December 8, 2010	Change Request: 7220

Transmittal 128, dated November 19, 2010, is being rescinded and replaced with Transmittal 129. The only change is in the Summary of Changes, the date of November 19, 2010, was incorrect, the correct date is November 9, 2010. Transmittal 129, issued December 8, 2010 is being re-issued to change the implementation date from December 9, 2010 to January 6, 2011. It was erroneously changed to December 9, 2010 and should have remained as January 6, 2011. The transmittal number, date issued and all other material remain the same.

SUBJECT: Ventricular Assist Devices (VADs) as Destination Therapy

EFFECTIVE DATE: **November 9, 2010**
IMPLEMENTATION DATE: January 6, 2011

I. GENERAL INFORMATION

A. Background: A ventricular assist device (VAD) or left ventricular assist device (LVAD) is surgically attached to one or both intact ventricles and is used to assist a damaged or weakened native heart in pumping blood. Medicare covers these devices for three general indications; postcardiotomy, bridge to transplantation and destination therapy. Destination therapy is for patients who are not candidates for heart transplantation and require permanent mechanical cardiac support. Coverage for destination therapy is restricted based on patient selection criteria including New York Heart Association (NYHA) class, time on optimal medical management, left ventricular ejection fraction and peak oxygen consumption. In addition, VADs implanted for destination therapy are only covered when performed in a hospital that is Medicare approved to provide this procedure.

The CMS is expanding the covered patient population as stated in the policy section below.

B. Policy: Effective for claims with dates of service on and after November 9, 2010, CMS has determined that the evidence is adequate to conclude that VAD implantation as destination therapy improves health outcomes and is reasonable and necessary when the device has received FDA approval for a destination therapy indication and only for patients with NYHA Class IV end-stage ventricular heart failure who are not candidates for heart transplant and who meet all of the following conditions:

A. Have failed to respond to optimal medical management (including beta-blockers, and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days;

B. Have a left ventricular ejection fraction (LVEF) < 25%; and,

C. 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.

NOTE: There are no changes to existing claims processing requirements/editing for VADs as destination therapy.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7220.1	Effective for claims with dates of service on and after November 9, 2010, contractors shall pay claims for VADs as destination therapy using the criteria in Pub. 100-03, chapter 1, section 20.9, and Pub. 100-04, chapter 3, section 90.2.1.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7220.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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 site 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 your 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	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Joanna Baldwin, Coverage, 410-786-7205, Joanna.Baldwin@cms.hhs.gov, Patti Brocato-Simons, Coverage, 410-786- 0261, Patricia.Brocatosimons@cms.hhs.gov, Cami DiGiacomo, Institutional Claims Processing, 410-786-5888, cami.digiacomo@cms.hhs.gov, Vera Dillard, Practitioner Claims Processing, 410-786-6149, vera.dillard@cms.hhs.gov

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: 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.

20.9 - Artificial Hearts and Related Devices (Various Effective Dates Below)

(Rev.129, Issued: 12-08-10, Effective: 11-09-10, Implementation: 01-06-11)

A. General

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

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. Postcardiotomy (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

a. VADs as 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 the 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 and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and,

- The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.

The Medicare-approved heart transplant center should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the Medicare-approved heart transplant centers should determine patient-specific timetables for transplantation, and should not maintain such patients on VADs if suitable hearts become available.

b. Artificial Heart*s* as Bridge-to-Transplant (effective for services performed on or after May 1, 2008)

An artificial heart for bridge-to-transplantation 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 and Medicaid Services Re: Artificial Heart, Mailstop C1-09-06, 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.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp.

3. Destination Therapy

a. VADs as Destination Therapy (effective for services performed on or after October 1, 2003, facility criteria updated March 27, 2007, *patient selection criteria updated November 9, 2010*).

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

Patient Selection

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, and meet all of the following conditions:

- *Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days;*

- *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

- Facilities must have at least one member of the VAD team with experience implanting at least 10 VADs (as bridge-to-transplant or destination therapy) or artificial hearts over the course of the previous 36 months;

- Facilities must be a member of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS); and,

- *Effective* March 27, 2009, all facilities must *have met* the above facility criteria and *been* credentialed by the Joint Commission under the Disease Specific Certification Program for Ventricular Assist Devices (standards dated February 2007).

The Web site: http://www.cms.hhs.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage *is* updated continuously to list all approved facilities. Facilities gaining Joint Commission certification (including prior to March 27, 2009) *are* added to the Web site when certification is obtained.

Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.

b. Artificial Hearts as Destination Therapy (effective for services performed on or after May 1, 2008)

An artificial heart for destination therapy 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 wide spread 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 and Medicaid Services, Re: Artificial Heart, Mailstop C1-09-06, 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.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp.

C. Nationally Non-Covered Indications (effective for services performed on or after May 19, 1986)

All other indications for the use of VADs or 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 NCD Manual.

D. Other

Clinical study criteria:

- *The study must be reviewed and approved by the 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 coverage with study participation (CSP) or CED coverage.*

- *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 ClinicalTrials.gov Web site by the principal sponsor/investigator as demonstrated by having a National Clinical Trial control number.*

- *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 underrepresented 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 underrepresented 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 the Centers for Medicare & Medicaid Services (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 registration number.*

(This NCD last reviewed November 2010.)