CMS Manual System	Department of Health & Human Services (DDHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 95	Date: SEPTEMBER 10, 2008
	Change Request 6185

This corrects Transmittal 93, Change Request 6185, dated August 29, 2008. The only change is the implementation date. All other material remains the same.

SUBJECT: Artificial Hearts

I. SUMMARY OF CHANGES: Medicare issued an NCD on May 1, 2008, establishing coverage for artificial hearts when implanted under CED. CMS will maintain a Web site that will list all studies approved to meet CED criteria. Coverage is only available when artificial hearts are implanted as part of one of the listed clinical studies.

In addition, CMS determines that MA Organizations will not be responsible for payment since coverage is only allowed under clinical studies. Claims for beneficiaries enrolled in MA plans should be sent to the appropriate FFS contractor and should include the appropriate codes to ensure proper payment.

This revision of sections 20.9 and 260.9 of Pub.100-03 is an NCD. NCDs are binding on all carriers, FIs, QIOs, QICs, the Medicare Appeals Council, and ALJs (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on an MA organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL
EFFECTIVE DATE: *MAY 1, 2008
IMPLEMENTATION DATE: DECEMBER 1, 2008

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/Table of Contents
R	1/20.9/Artificial Hearts and Related Devices – (Various Effective Dates Below)
R	1/260.9/Heart Transplants

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their

operating budgets.

SECTION B: 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: 95	Date: September 10, 2008	Change Request: 6185

This corrects Transmittal 93, Change Request 6185, dated August 29, 2008. The only change is the implementation date. All other material remains the same.

SUBJECT: Artificial Hearts

Effective Date: May 1, 2008
Implementation Date: December 1, 2008

I. GENERAL INFORMATION

A. Background: Medicare issued a national coverage determination (NCD) on May 1, 2008, that establishes limited coverage for artificial hearts under Coverage with Evidence Development (CED). Prior to May 1, 2008, the use of artificial hearts was not covered by Medicare as determined by the Centers for Medicare & Medicaid Services' (CMS') NCD effective May 19, 1986.

B. Policy: Medicare will cover artificial hearts when implanted in patients enrolled in clinical studies that have been approved by Medicare to meet all of the CED criteria. CMS will maintain a Web site (http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage) that will list all approved artificial heart studies. Coverage under CED will only apply to artificial hearts that are implanted in the context of one of the approved clinical studies listed on the above-noted Web site.

In addition, CMS has determined that since coverage is only available under clinical studies, the billing and coding requirements will be the same as what is currently used for other Medicare covered clinical trials under the Clinical Trials NCD effective 2007. This includes the current policy as it relates to Medicare managed care organizations in that they will not be responsible for payment for the artificial heart or for routine services related to the study until such time that the plans capitated rate has been appropriately adjusted to include them (see 42 CFR 422.109). Therefore, claims pertaining to the routine costs, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in the trial, and claims for managed care beneficiaries receiving services in an approved clinical study for artificial hearts, should be sent to the appropriate fee-for-service contractor. Institutional and physician/supplier claims for routine services provided in approved artificial heart studies should be billed and processed according to previously issued instructions for clinical trials.

Institutional claims for International Classification of Diseases, 9th edition (ICD-9) procedure code 37.52 are only payable when they include ICD-9 diagnosis code V70.7 (examination of participant in clinical research) and condition code 30 (qualifying clinical trial). The 8-digit National Clinical Trial Number is required (the trial number must match an approved trial).

Physician/supplier claims for Common Procedural Terminology (CPT) code 0051T are only payable when they include ICD-9 diagnosis code V70.7 and HCPCS modifier Q0. As noted above, the 8-digit National Clinical Trial number is also required.

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	
6185A.1	Effective for discharges on or after May 1, 2008, claims containing ICD-9 procedure code 37.52 shall only be paid when all the following are present: • Diagnosis code V70.7 (as secondary diagnosis) • Condition code 30 • Value Code D4 with an 8-digit clinical trial number that matches an approved clinical trial listed at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage	X		X			X			X	
6185A.2	Contractors shall reject claims with ICD-9 procedure code 37.52 that do not meet all the necessary billing criteria outlined in 6185A.1.	X		X			X			X	
6185A.2.1	Contractors shall use the following Claim Adjustment Reason Code (CARC) when ICD-9 procedure code 37.52 is present on a claim without all the required elements: **16** - Claim/service lacks information which is needed for adjudication.	X		X							
6185A.2.2	Contractors shall use the following Remittance Advice Remark Codes (RARCs) when applicable: For a missing/incomplete/invalid clinical trial number when ICD-9 procedure code 37.52 is billed, use the following RARC: **MA97** – Missing/ incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number. For a missing V70.7 diagnosis code when ICD-9 procedure code 37.52 is billed, use the following RARC: **M64** – Missing/incomplete/invalid other diagnosis. For a missing Condition code 30 when ICD-9 procedure code 37.52 is billed, use the following RARC: **M44** – Missing/incomplete/invalid condition code.	X		X							

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	
6185A.2.3	Contractors shall use the following Medicare Summary Notice (MSN) when claims with ICD-9 procedure code 37.52 are rejected for not meeting the necessary billing requirements: **21.21** - This service was denied because Medicare only covers this service under certain circumstances. **21.21** - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.	X		X							
6185A.3	Effective for dates of service on or after May 1, 2008, claims containing CPT code 0051T shall only be paid when all the following are present: • Diagnosis code V70.7 (as primary diagnosis) • HCPCS modifier Q0 • An 8-digit clinical trial number that matches an approved clinical trial listed at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage **NOTE:** The HCPCS modifier Q0 must be on the same claim line as CPT code 0051T.	X			X			X		X	
6185A.4	Contractors shall return as unprocessable claims with CPT code 0051T that do not meet all the necessary billing criteria outlined in 6185A.3.	X			X						
6185A.4.1	Contractors shall use CARC **16** (Claim/service lacks information which is needed for adjudication) when CPT code 0051T is present on a claim without the required diagnosis code or 8-digit clinical trial number.	X			X						
6185A.4.2	Contractors shall use RARC **MA 130** (Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.) when CPT code 0051T is present on a claim without the required diagnoses code or 8-digit clinical trial number.	X			X						

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	
6185A.4.3	Contractors shall use the following RARCs when applicable: For a missing clinical trial number when CPT code 0051T is billed, use the following RARC: **MA97** – Missing/incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number. For a missing V70.7 diagnosis code when CPT code 0051T is billed, use the following RARC: **M64** – Missing/incomplete/invalid other diagnosis.	X			X						
6185A.4.4	Contractors shall use the following CARC when there is no HCPCS modifier Q0 appended to CPT code 0051T: **4** – The procedure code is inconsistent with the modifier used or a required modifier is missing	X			X						
6185A.4.5	Contractors shall use the following RARC when there is no HCPCS modifier Q0 appended to CPT code 0051T: **MA130** - Your claim contains incomplete and/or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.	X			X						
6185A.5	Contractors shall pay claims for beneficiaries enrolled in Medicare managed care plans for investigational and routine services provided as part of approved artificial heart clinical studies.	X		X	X		X	X		X	
6185A.6	Contractors shall establish a mechanism to hold claims outlined in 6185A.1 and 6185A.3 until the claims can be correctly processed.	X		X	X		X	X			
6185A.6.1	Contractors shall release and finalize any held claims upon successful implementation of this CR.	X			X						
6185A.6.2	Contractors shall pay interest as appropriate on held claims.	X		X	X		X	X			
6185A.7	Contractors shall release and finalize any held claims upon successful implementation of this CR and the FY 2009 Medicare Code Editor.	X		X							

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	
6185A. 7.1	Contractors shall append condition code 15 to claims upon release to exempt them from CMS' claims processing timeliness standards.	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	
6185A.8	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:

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: JoAnna Baldwin at 410-786-7205 or joanna.baldwin@cms.hhs.gov
Institutional Claims Processing: Joe Bryson at 410-786-2986 or joseph.bryson@cms.hhs.gov
Practitioner Claims Processing: Vera Dillard at 410-786-6149 or vera.dillard@cms.hhs.gov

Post-Implementation Contact(s): Regional office

VI. FUNDING

Section A: 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.

Section B: *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.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)
Coverage Determinations

Table of Contents
(Rev. 95, 09-10-08)

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

(Rev. 95; Issued:09-10-08 ; Effective Date: 05-01-08; Implementation Date: 12-01-08)

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:

a. The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center; and,

b. 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 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 following 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 website 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 (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.*

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, with facility criteria updated March 27, 2007)

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, and the device is used according to the FDA-approved labeling instructions.

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 for at least 90 days with a life expectancy of less than 2 years), are not candidates for heart transplantation, and meet all of the following conditions:

a. The patient's Class IV heart failure symptoms have failed to respond to optimal medical management, including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors (if tolerated) for at least 60 of the last 90 days;

b. The patient has a left ventricular ejection fraction (LVEF) <25%;

c. The patient has demonstrated functional limitation with a peak oxygen consumption of <12 ml/kg/min; or the patient has a continued need for intravenous inotropic therapy owing to symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion; and,

d. The patient has the appropriate body size ($\geq$1.5 m^2) to support the VAD implantation.

Facility Criteria

a. 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;

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

c. By March 27, 2009, all facilities must meet the above facility criteria and be 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 will be updated continuously to list all approved facilities. Facilities gaining Joint Commission certification (including prior to March 27, 2009) will be 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 Heart 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 following 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 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 website 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 (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 on 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 Act, 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 registration number.*

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.
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 IDE clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual..

(This NCD last reviewed April 2008.)

260.9 - Heart Transplants
(Rev. 95; Issued: 09-10-08; Effective Date: 05-01-08; Implementation Date: 12-01-08)

A. General

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. (See CMS Ruling 87-1.)

B. Exceptions

In certain limited cases, exceptions to the criteria may be warranted if there is justification and if the facility ensures our objectives of safety and efficacy. Under no circumstances will exceptions be made for facilities whose transplant programs have been in existence for less than 2 years, and applications from consortia will not be approved.

Although consortium arrangements will not be approved for payment of Medicare heart transplants, consideration will be given to applications from heart transplant facilities that consist of more than one hospital where all of the following conditions exist:

- The hospitals are under the common control or have a formal affiliation arrangement with each other under the auspices of an organization such as a university or a legally constituted medical research institute; and

- The hospitals share resources by routinely using the same personnel or services in their transplant programs. The sharing of resources must be supported by the submission of operative notes or other information that documents the routine use of the same

personnel and services in all of the individual hospitals. At a minimum, shared resources means:

- The individual members of the transplant team, consisting of the cardiac transplant surgeons, cardiologists and pathologists, must practice in all the hospitals and it can be documented that they otherwise function as members of the transplant team; and

- The same organ procurement organization, immunology, and tissue-typing services must be used by all the hospitals;

- The hospitals submit, in the manner required (Kaplan-Meier method) their individual and pooled experience and survival data; and

- The hospitals otherwise meet the remaining Medicare criteria for heart transplant facilities; that is, the criteria regarding patient selection, patient management, program commitment, etc.

C. Pediatric Hospitals

Cardiac transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric heart transplants if the hospital submits an application which CMS approves as documenting that:

- The hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in CMS Ruling 87-1;

- The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and

- The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

D. Follow-Up Care

Follow-up care required as a result of a covered heart transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered heart transplant. Coverage for follow-up care would be for items and services that are reasonable and necessary, as determined by Medicare guidelines. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §180.)

E. Immunosuppressive Drugs

See the Medicare Claims Processing Manuals, Chapter 17, “Drugs and Biologicals,” §§80.3.1 and, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §120.1.

F. Artificial Hearts

Medicare covers ventricular assist devices (VAD) and artificial hearts when implanted under the coverage criteria stated in §20.9 of this manual (NCD Manual 100-03).

(This NCD last reviewed April 2008.)