

Medicare Coverage Database	NCD for Artificial Hearts and Related Devices (20.9)
<ul style="list-style-type: none"> » Overview » Search » Indexes » Reports » Downloads » Basket » MCD Help 	<p>Publication Number</p> <p>100-3</p> <p>Manual Section Number</p> <p>20.9</p> <p>Version Number</p> <p>4</p> <p>Effective Date of this Version</p> <p>5/1/2008</p> <p>Implementation Date</p> <p>12/1/2008</p> <p>Benefit Category</p> <p>Prosthetic Devices</p> <p>Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.</p> <p>Item/Service Description</p> <p>A. General</p> <p>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.</p> <p>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.</p> <p>Indications and Limitations of Coverage</p> <p>B. Nationally Covered Indications</p> <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> a. VADs as Bridge-to-Transplant (effective for services performed on or after January 22, 1996) <p>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:</p> <ol style="list-style-type: none"> 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.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:

- 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;
- The patient has a left ventricular ejection fraction (LVEF) < 25%;
- 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,
- The patient has the appropriate body size (>1.5 m²) to support the VAD implantation.

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,
- 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.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.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.)

Transmittal Number

95

Transmittal Link<http://www.cms.gov/transmittals/downloads/R95NCD.pdf> **Revision History**

05/1986 – Specified that artificial hearts not covered, either as permanent replacements or as temporary life-support systems. Also, ventricular assist devices (VADs) not covered when used as temporary life-support systems in patients awaiting heart transplants. Effective date 05/19/1986. (TN 7)

10/1993 – Provided coverage of FDA-approved VAD only when used in patients suffering from postcardiotomy ventricular dysfunction. Device intended for short use and not covered when used as bridge to cardiac transplantation. Effective date 10/18/1993. (TN 65)

11/1995 – Removed "not covered" from title, and allowed exception for HeartMate IP LVAS when used as bridge to cardiac transplantation. Effective date 01/22/1996. (TN 82)

04/1997 – Clarified that VADs covered only if FDA approval received and used according to FDA-approved labeling instructions. Also deleted specific product names and hemodynamic criteria. Effective date 05/05/1997. (TN 94)

12/2000 – Allowed sites other than Medicare approved heart transplant centers to implant VADs in patients approved and listed as candidates for heart transplant by Medicare approved heart transplant center. Also, implanting site must receive written permission from Medicare approved heart transplant center under which patient is listed prior to implantation of VAD. Effective and implementation dates 01/01/2001. ([TN 134](#) ) (CR 1378)

10/2003 – Expanded coverage of VADs for destination therapy if FDA approval received for that purpose, used according to FDA-approved labeling instructions, patient meets specified criteria, and procedure performed in specified facilities. All other indications remain the same. Effective and implementation dates 10/01/2003. ([TN 2](#) ) (CR 2958)

11/2003 – Issued provider education article that discusses expansion in coverage of VADs for destination therapy. Effective date 10/01/03. Implementation date 11/21/03. ([TN 4](#) ) (CR 2985)

04/2007 – New facility criteria is established and hospitals must now receive certification from the Joint Commission on Accreditation of Healthcare Organizations under their Disease Specific Certification Program for VADs. Currently approved hospitals will have until March 27, 2009, to become certified by the Joint Commission or they will be removed from the approved list. Effective date 03/27/2007. Implementation date 05/14/2007. ([TN68](#) ) (CR5516)

08/2008 – Established 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 list clinical studies. Effective date 05/01/2008. Implementation date 10/06/2008. ([TN93](#) ) (CR6185)

09/2008 – This corrects Transmittal 93, Change Request 6185, dated August 29, 2008. **The only change is the implementation date(12/01/2008)**. All other material remains the same. ([TN95](#) )

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- [Original consideration for Artificial Hearts \(CAG-00322N\)](#)
- [Original consideration for Ventricular Assist Devices \(VADs\) as a Bridge to Heart Transplantation \(CAG-00162N\)](#)
- [Original consideration for Ventricular Assist Devices as Destination Therapy \(CAG-00119N\)](#)
- [First reconsideration for Ventricular Assist Devices as Destination Therapy \(CAG-00119R\)](#)
- [Second reconsideration for Ventricular Assist Devices as Destination Therapy \(CAG-00119R2\)](#)

Other Versions

[Artificial Hearts and Related Devices](#) – Version 3, Effective between 03/27/2007 – 05/01/2008

[Artificial Hearts and Related Devices](#) – Version 2, Effective between 10/01/2003 – 03/27/2007

[Artificial Hearts and Related Devices](#) – Version 1, Effective between 01/01/2001 – 10/01/2003

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