

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

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WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Total Artificial Heart Devices

Guideline Number: HS-074

Original Effective Date: 1/12/2009

Revision Date: 1/29/2010; 1/21/2011

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Artificial hearts, whether used as 1) a bridge to transplantation in members who are transplant-eligible or 2) destination therapy, are considered investigational and NOT a covered benefit.

However, WellCare has determined that the evidence reviewed suggests that the use of artificial hearts has the potential to improve health outcomes for members and supports additional research for these devices. Therefore, the artificial heart **WILL BE COVERED** under Medicare's Coverage with Evidence Development (CED) provision when members are enrolled in a clinical study that meets **ALL** of the criteria listed below.

*The clinical study utilizing the artificial heart must meet **ALL** of the following criteria:

- The study must be reviewed and approved by the FDA.
- The principal purpose of the study must test whether a particular intervention potentially improves health outcomes.
- The study must be 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 study must not duplicate existing studies.
- The study design is appropriate to answer the research question being asked.
- The study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The study must comply with all federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
- All aspects of the study must be conducted according to appropriate standards of scientific integrity.
- The study must have a written protocol that clearly addresses the standards listed as Medicare requirements.
- The study must not be designed to test toxicity or disease pathophysiology in healthy individuals. The study must study a disease with no other viable treatment options.
- The study is registered on clinicaltrials.gov by the principle investigator.
- The study protocol specifies the method and timing of public release of all outcomes to be measured. The results must be made public within 24 months after the end of data collection.

- The protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies.
- The protocol must explicitly discuss how the results are or are not expected to be generalizable to the overall population, so possible benefits can be inferred.

BACKGROUND

Artificial Heart Devices

The artificial heart devices under consideration fall into two distinct patient health outcome categories: 1) bridge to transplant, and 2) destination therapy. Below the devices under consideration are described.

The CardioWest™ (Syncardia Systems Inc) TAH-t is FDA approved as a *bridge to transplant*. If the member is in severe biventricular Class IV heart failure, they meet requirements to be listed for a heart transplant. With successful implantation of the artificial heart and appropriate care until a donor heart becomes available, they would be expected to achieve long-term survival following transplant. Thus, the outcomes concerning this population are a successful artificial heart implantation, survival to a successful transplant and continued survival thereafter without negative effects from adverse events such as device failure, infections, excessive bleeding or neurological consequences.

The AbioCor® Implantable Replacement Heart System (ABIOMED Inc) is FDA approved for *destination therapy* for members who are not candidates for heart transplantation and are near death from end stage biventricular Class IV heart failure. These members have exhausted all other treatment options and the purpose of the artificial heart is to prolong their lives and hopefully permit meaningful quality of life (e.g., discharge from hospital to home). The outcomes of interest for this group of members are increased survival, discharge to the home and a successful implantation of the artificial heart without such adverse events as device failure, infection, excessive bleeding or neurological consequences. Since the mean length of survival for these patients thus far has been 4.5 months, improving that duration and assuring that most members are discharged to home are important outcomes (CMS Decision Memo, 2008).

Professional Statements

After review of the evidence, CMS released the following statement in a 2008 Decision Memo: “CMS believes that the evidence reviewed suggests that the use of artificial hearts has a high potential to improve health outcomes for Medicare beneficiaries and *supports additional research for these devices*. Therefore, the artificial heart will be covered by Medicare under Coverage with Evidence Development when the study meets the criteria detailed in Section I of this document.”

In addition, a consensus statement from the American College of Cardiology (ACC), American Heart Association (AHA), International Society for Heart and Lung Transplantation (ISHLT), American Society of Transplantation (AST), Heart Failure Society of America (HFSA), American Association for Thoracic Surgery (AATS), the Society of Thoracic Surgeons (STS), and the American Society of Transplant Surgeons (ASTS) concluded that “implantable devices have been shown to be safe and effective as bridges to heart transplantation, *but further research is needed* to establish the role of mechanical support for myocardial recovery and long-term support.”

CODING

Wellcare has determined that the total artificial heart **WILL BE COVERED** under Medicare’s Coverage with Evidence Development (CED) provision when members are enrolled in a clinical study that meets **ALL** of the criteria listed above.

CPT® Codes

No applicable codes for the total artificial heart.

Category III CPT® Codes

0051T Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy

0052T Replacement or repair of thoracic unit of a total replacement heart system (artificial heart)

0053T Replacement or repair of implantable component or components of total replacement heart system

HCPCS Level II Modifiers apply as outlined in the CMS instructions below.

QO - Investigational clinical service provided in a Clinical Research Study that is an approved clinical research study

Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study

HCPCS Level II © Codes

No applicable codes for total artificial heart.

ICD-9-CM Procedure Codes

37.52 Implantation of Total Internal Biventricular heart replacement system; Artificial Heart

Note: This procedure includes substantial removal of part or all of the biological heart. Both ventricles are resected and the native heart is not longer intact. Ventriculectomy is included in this procedure; do not code separately.

37.53 Replacement or repair of thoracic unit of total replacement heart system

37.54 Replacement or repair of other implantable component of total replacement heart system

ICD-9-CM Diagnosis Code

V70.7 Examination of participant or control in clinical research

428.0 Congestive Heart Failure, unspecified

428.40 Combined systolic and diastolic heart failure, unspecified

428.41 Acute Combined Systolic & Diastolic Heart Failure

428.42 Chronic Combined Systolic and Diastolic Heart Failure

428.43 Acute on Chronic Combined Systolic and Diastolic Heart Failure

V49.83 Awaiting organ transplant status

Condition Code as outlined in the CMS instructions below.

30 Qualifying Clinical Trial

National Clinical Trial Number as outlined in the CMS instructions below.

Value Code D4, with an 8-digit National Clinical Trial Number that matches the approved clinical trial on the CMS website is also required.

Coding Requirements for artificial hearts in clinical trials per CMS:

The following addresses the institutional and physician/supplier coding requirements for coverage of artificial hearts in clinical trials:

1. Institutional Claims

Effective for discharges on or after May 1, 2008, institutional claims for International Classification of Diseases, 9th edition (ICD-9) procedure code 37.52 are only payable when you include ICD-9 diagnosis code V70.7 (examination of participant in clinical research) and condition code 30 (qualifying clinical trial). In addition, Value Code D4, with an 8-digit National Clinical Trial Number that matches an approved clinical trial on the CMS

website provided above, is also required.

If your FI or A/B MAC rejects your claim with ICD-9 procedure code 37.52, because it does not meet all of these necessary billing criteria, they will use:

- **Claim Adjustment Reason Code (CARC) 16 – Claim/service lacks information which is needed for adjudication**, when ICD-9 procedure code 37.52 is present on a claim without all the required elements; and
- The following **Remittance Advice Remark Codes (RARCs)**, when applicable
 - **MA97 – Missing/incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number**, for a missing/incomplete/invalid clinical trial number when ICD-9 procedure code 37.52 is billed;
 - **M64 – Missing/incomplete/invalid other diagnosis**, for a missing V70.7 diagnosis code when ICD-9 procedure code 37.52 is billed; or
 - **M44 – Missing/incomplete/invalid condition code**, for a missing Condition code 30 when ICD-9 procedure code 37.52 is billed.

2. Physician/Supplier claims

Effective for dates of service on or after May 1, 2008, physician/supplier claims for Common Procedural Terminology (CPT) code 0051T must include ICD-9 diagnosis code V70.7 and Healthcare Common Procedure Coding System (HCPCS) modifier Q0 on the same claim line as CPT Code 0051T, and must also include the 8-digit clinical trial number that matches an approved clinical trial on the CMS website provided above.

If your carrier or A/B MAC returns your claim with CPT code 0051T as unprocessable because it does not meet all of these necessary billing criteria, they will 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;
- **CARC 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing**, when there is no HCPCS modifier Q0 appended to CPT code 0051T;
- **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 there is no HCPCS modifier Q0 appended to CPT code 0051T; and

The following RARCs when applicable:

- **MA97 – Missing/ incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number, for a missing/incomplete/invalid clinical trial number** when CPT code 0051T is billed without the 8-digit clinical trial number; or
- **M64 – Missing/incomplete/invalid other diagnosis**, for a missing V70.7 diagnosis code when CPT code 0051T is billed without the V70.7 diagnosis code.

3. Additional Inpatient and Outpatient Claims Instructions Related to Clinical Trial Patients

Inpatient Claims

Institutional providers billing clinical trial service(s) must report a diagnosis code V70.7 and a condition code 30 regardless of whether all services are related to the clinical trial or not.

Note: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Claims

- Institutional providers billing clinical trial claims that contain only clinical trial line item services do not have to report the routine modifier Q1. The presence of condition code 30, along with the absence of the Q1 modifier, is the provider's attestation that all line item services on the claim are routine clinical trial services (with the exception of any investigational item on the claim that would be identified with a Q0 modifier on or after January 1, 2008).
- Institutional providers billing clinical trial claims that contain both clinical trial line item services and non-clinical trial line item services, must bill the following elements:

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier 'Q1' only on line items related to the clinical trial
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis
- Condition Code 30

CR 6185 was issued in two separate transmittals, one for conveying changes to the Medicare NCD Manual and one for changes to the Medicare Claims Processing Manual. These transmittals are available at <http://www.cms.hhs.gov/Transmittals/downloads/R95NCD.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R1592CP.pdf>, respectively, on the CMS Web site. The revised portions of each manual are attached to the respective transmittals.

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