ARTIFICIAL HEARTS AND RELATED DEVICES (NCD 20.9)

Guideline Number: MPG019.05
Approval Date: August 8, 2018

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Related Medicare Advantage Policy Guidelines

- Percutaneous Ventricular Assist Device
- Routine Costs in Clinical Trials (NCD 310.1)
- Ventricular Assist Devices (NCD 20.9.1)

Related Medicare Advantage Coverage Summaries

- Experimental Procedures and Items, Investigational Devices and Clinical Trials
- Ventricular Assist Device (VAD) and Artificial Heart

Related Medicare Advantage Reimbursement Policy

- Surgical Assistant Services Policy

POLICY SUMMARY

Overview
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.

Guidelines
Nationally Covered Indications

- Artificial Hearts as Bridge-to-Transplant
  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:
    o 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?
    o What will be the average time to device failure when the device is made available to larger numbers of patients?
    o 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 the Other section of this overview.

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 website at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html.

- Artificial Hearts as Destination Therapy
  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:
    o 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?
    o What will be the average time to device failure when the device is made available to larger numbers of patients?
    o 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 the Other section of this overview.
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 https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Artificial-Hearts.html.

### Nationally Non-Covered Indications

All other indications for the use of artificial hearts not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the NCD Manual.

### 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 (http://clinicaltrials.gov/) 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.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

**Coding Clarification:** CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study. The clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED). Specifically, include the clinical trial identifier number if:
- The beneficiary is enrolled in an approved clinical trial; and
- The claim is for the investigational item or service, and/or
- The costs are related to the investigational item or service, and/or
- The costs are related to routine care for the condition in the clinical trial.
See the related MLN Matters.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33927</td>
<td>Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy (coverage with a clinical trial only) <em>(Effective 01/01/2018)</em></td>
</tr>
<tr>
<td>33928</td>
<td>Removal and replacement of total replacement heart system (artificial heart) <em>(Effective 01/01/2018)</em></td>
</tr>
<tr>
<td>33929</td>
<td>Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure) <em>(Effective 01/01/2018)</em></td>
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*CPT® is a registered trademark of the American Medical Association*

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>CED Only</td>
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<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study in an approved clinical research study (Outpatient only)</td>
</tr>
<tr>
<td>Q1</td>
<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study (Outpatient only)</td>
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<thead>
<tr>
<th>Condition Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CED Only</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Qualifying clinical trial (Inpatient only)</td>
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<table>
<thead>
<tr>
<th>ICD-10 Procedure Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>02RK0JZ</td>
<td>Replacement of right ventricle with synthetic substitute, open approach</td>
</tr>
<tr>
<td>02RL0JZ</td>
<td>Replacement of left ventricle with synthetic substitute, open approach</td>
</tr>
<tr>
<td>02WA0JZ</td>
<td>Revision of Synthetic substitute in heart, open approach</td>
</tr>
</tbody>
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**QUESTIONS AND ANSWERS**

<table>
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<tr>
<th>Q: Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)?</th>
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<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>• If no, clinical trial number, modifier Q0 or Q1 and diagnosis code Z00.6 should not be submitted.</td>
</tr>
<tr>
<td>• If yes, the three requirements listed above are required. Claims without the required information will be denied.</td>
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</tbody>
</table>
PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

• Medicare coding or billing requirements, and/or
• Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 20.9 Artificial Hearts and Related Devices
Reference NCDs: NCD 20.9.1 Ventricular Assist Devices, NCD 310.1 Routine Costs in Clinical Trials

CMS Benefit Policy Manual
Chapter 15; § 232 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

CMS Claims Processing Manual
Chapter 32; § 68 Investigational Device Exemption (IDE) Studies, § 69 Qualifying Clinical Trials, § 140 Cardiac Rehabilitation Programs, Intensive Cardiac Rehabilitation Programs, and Pulmonary Rehabilitation Programs; § 320 Artificial Hearts and Related Devices

CMS Transmittals
Transmittal 1975, Change Request 10318, Dated 11/09/2017, ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
Transmittal 2005, Change Request 10318, Dated 01/18/2018, ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)

MLN Matters
Article MM8401, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims
Article SE1344, Further Information on Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

UnitedHealthcare Commercial Policies
Total Artificial Heart

Others
CMS Approved Clinical Trials for Artificial Hearts, CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>08/08/2018</td>
<td>• Annual review</td>
</tr>
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</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.
Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.