Medicare Coverage of Artificial Hearts – JA6185

Related CR Release Date : September 10, 2008	Date Job Aid Revised: September 19, 2008
Effective Date: May 1, 2008	Implementation Date: December 1, 2008

Key Words	MM6185, CR6185, R95NCD, R1592CP, Artificial, Heart
Contractors Affected	• Medicare Carriers • Fiscal Intermediaries (FIs) • Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Physicians, providers, and suppliers who bill Medicare Carriers, FIs, and A/B MACs for cardiac-related services and supplies to Fee-for-Service (FFS) Medicare beneficiaries and Managed Care Plan Medicare beneficiaries

Change Request (CR) 6185 announces that Medicare has issued a national coverage determination (NCD) (effective on May 1, 2008) that establishes limited coverage for artificial hearts when implanted in patients enrolled in Medicare-approved clinical studies meeting all of the Coverage with Evidence Development (CED) criteria.

Provider Needs to Know...

- CR6185 announces that Medicare has issued an NCD that establishes limited coverage for artificial hearts as a bridge-to-transplantation and as destination therapy, under CED.
- This means that Medicare will cover artificial hearts when implanted in patients enrolled in Medicare-approved clinical studies that meet all of the CED criteria.
- Therefore, the artificial heart will be covered by Medicare under Coverage with Evidence Development when beneficiaries are enrolled in a clinical study that meets all of the criteria as listed in the updated *NCD Manual* at Section 20.9, which is attached to CR6185.

Billing Requirements

- Claims related 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 FFS contractor and include the appropriate codes to ensure proper payment.
- 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.
- Medicare contractors will hold claims until CR6185 is implemented and the claims can be correctly processed. Upon successful implementation of CR6185, Medicare contractors will process the claims and pay interest (as appropriate) on held claims.
- CMS has also determined that since coverage is only available under clinical studies, the billing and coding requirements will be the same as those currently used for other Medicare-covered clinical trials as included in the NCD effective September 2000. This means that Medicare Advantage organizations will not be responsible for payment for the artificial heart, or for routine services related to the study, until a plan's capitated rate has been appropriately adjusted to include them.

Coding Requirements

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

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 the provider includes 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 ***http://clinicaltrials.gov/*** on the CMS website is also required.
- If a FI or A/B MAC rejects a 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.

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. They must also include the 8-digit clinical trial number that matches an approved clinical trial on ***http://clinicaltrials.gov/*** on the CMS website.
- If the carrier or A/B MAC returns the provider's claim with CPT code 0051T as unprocessable because it does not meet all of these necessary billing criteria, they will use:

  CARC Codes

  - 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 Codes

  - 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;
    - 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.

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.
- HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or 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 modifiers, QV or Q1. The presence of condition code 30, along with the absence of the QV or 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, or a QA modifier before 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 before January 1, 2008:
    - HCPCS modifier 'QV' only on line items related to the clinical trial;
    - Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis; and
    - Condition code 30.
  - 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; and
    - Condition code 30.

Message to Principal Investigator (PI)

- Finally, if the provider is the PI of an artificial heart clinical study seeking Medicare payment, s/he should submit the following documentation to CMS (who will notify him/her when the review is complete):
  - The complete study protocol (must be dated or identified with a version number);
  - The protocol summary;
  - A statement that the submitted protocol version has been agreed upon by the Food and Drug Administration;
  - A statement that the clinical study standards are met;
  - A statement that the study addresses at least one of the questions related to artificial hearts;
  - Complete contact information (phone number, email address, and mailing address); and
  - The *Clinicaltrials.gov* registration number.

- The PI should send this information to:

  Director, Coverage and Analysis Group
  Centers for Medicare & Medicaid Services
  Re: Artificial Heart
  Mailstop C1-09-06
  7500 Security Boulevard
  Baltimore, MD 21244-1850

Background

- As determined by the May 19, 1986, Centers for Medicare & Medicaid Services (CMS) NCD, the use of artificial hearts was not covered by Medicare prior to May 1, 2008.
- The Agency for Healthcare Research and Quality supports clinical research studies that CMS has determined meet the standards, and address the research questions, that are listed in a decision memo for artificial hearts at *https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=211&* on the CMS website. These questions are also listed in the updated *NCD Manua*l at Section 20.9, which is attached to CR6185.
- Clinical studies that CMS has determined to have met these requirements will be listed at *http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp* on the CMS website, and coverage under CED will only apply to artificial hearts that are implanted in the context of one of these approved clinical studies.

Operational Impact

N/A

Reference Materials

The related MLN Matters article can be found at *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6185.pdf* on the CMS website.

CR6185 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 website. The revised portions of each manual are attached to the respective transmittals.