Medicare Learning Network
MLN Matters
CMS
Information for Medicare Fee-for-Service Health Care Professionals

News Flash - **Physician Quality Reporting Initiative (PQRI)** - The Centers for Medicare & Medicaid Services (CMS) is pleased to announce that a new educational resource has been posted to the PQRI webpage on the CMS website and is available for ordering through the Medicare Learning Network product ordering system. The *2008 PQRI Reporting Options Quick Reference Chart* is a two-sided laminated reference chart, which gives eligible professionals and practice staff a quick reference to the new reporting options available for 2008 PQRI with their corresponding alternative reporting periods. To access this new educational resource, visit *http://www.cms.hhs.gov/PQRI* on the CMS website and click on the Educational Resources tab. Once on the *Educational Resources* page, scroll down to the "Downloads" section and click on the "2008 PQRI Quick Reference Chart" link. To order the laminated product, visit *http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5* on the CMS website and click on the 2008 Physician Quality Reporting Initiative (PQRI) Reporting Quick Option Reference Chart (ICN# 900843)(May 2008) link.

MLN Matters Number: MM6185 Revised
Related Change Request (CR) #: 6185
Related CR Release Date: September 10, 2008
Effective Date: May 1, 2008
Related CR Transmittal #: R95NCD and R1592CP
Implementation Date: December 1, 2008

Medicare Coverage of Artificial Hearts

Note: This article was revised on September 11, 2008, to reflect changes made to CR6185. The CR was changed to revise the implementation date to December 1, 2008. In addition, the transmittal numbers, CR release date, and the Web addresses for accessing CR6185 were revised. All other information remains the same.

Provider Types Affected

Physicians, providers, and suppliers who bill Medicare contractors (carriers, fiscal intermediaries (FIs), and Medicare Administrative Contractors (A/B MACs)) for cardiac-related services and supplies to Fee-for-Service (FFS) Medicare beneficiaries and Managed Care Plan Medicare beneficiaries.

What You Need to Know

CR 6185, from which this article is taken, 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.

Make sure that your billing staffs are aware of these artificial heart coverage and billing instructions in CR 6185. Details are presented in Background, below.

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. CR 6185 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 listed below.

For your reference, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS has determined meet the standards, and address the research questions, that are listed below. 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.

To be approved, a clinical study must:

1. 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?

And

2. The clinical study must meet all of the following criteria:

- It must be reviewed and approved by the Food and Drug Administration (FDA);
- Its principal purpose is to test whether a particular intervention potentially improves the participants' health outcomes;

- It is well supported by available scientific and medical information, or is intended to clarify or establish the health outcomes of interventions already in common clinical use;
- It does not unjustifiably duplicate existing studies;
- Its design is appropriate to answer the research question being asked in the study;
- It is sponsored by an organization, or individual, capable of executing the proposed study successfully;
- It 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 are conducted according to appropriate standards of scientific integrity (see *http://www.icmje.org* on the Internet;
- It 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;
- It 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 Section 312.81(a) and the patient has no other viable treatment options);
- It is registered at *http://clinicaltrials.gov/* on the ClinicalTrials.gov website by the principal sponsor/investigator as demonstrated by having a National Clinical Trial control number;
- The research protocol must:

    - Specify 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, which can be found at *http://www.icmje.org* on the Internet. However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.);
    - 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 these 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, it must discuss why these criteria are necessary;

- Explicitly discuss 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.

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.

Your Medicare contractor will hold your claims until CR 6185 is implemented and the claims can be correctly processed. Upon successful implementation of CR 6185, 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 (MA) 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:

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., 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
  - 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
  - Condition Code 30

Message to Principal Investigator (PI)

Finally, if you are the PI of an artificial heart clinical study seeking Medicare payment, you should submit the following documentation to CMS (who will notify you 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 FDA;
- A statement that the above study standards are met;
- A 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,
- 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

Additional Information

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.

If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at *http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip* on the CMS Web site.