CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1592	Date: SEPTEMBER 10, 2008
	Change Request 6185

This corrects Transmittal 1583, Change Request 6185, dated August 29, 2008. The only change is the implementation date. All other material remains the same.

SUBJECT: Artificial Hearts

I. SUMMARY OF CHANGES: Medicare issued a national coverage determination on May 1, 2008, that establishes coverage for artificial hearts when implanted under Coverage with Evidence Development (CED). The Centers for Medicare and Medicaid Services (CMS) will maintain a Web site that will list all studies that are approved to meet CED criteria. Coverage is only available when artificial hearts are implanted as part of one of the listed clinical studies.

In addition, CMS determines that Medicare Advantage (MA) Organizations will not be responsible for payment since coverage is only allowed under clinical studies. Claims for beneficiaries enrolled in MA plans should be sent to the appropriate fee-for-service contractor and the claims should include the appropriate codes to ensure proper payment.

NEW/REVISED MATERIAL
EFFECTIVE DATE: MAY 1, 2008
IMPLEMENTATION DATE: DECEMBER 1, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/80.3.2.1.3/Carrier Specific Requirements for Certain Specialties/Services
R	3/90.2.1/Artificial Hearts and Related Devices
R	32/Table of Contents
R	32/69.6/Requirements for Billing Routine Costs of Clinical Trials

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Not Applicable.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1592	Date: September 10, 2008	Change Request: 6185

This corrects Transmittal 1583, Change Request 6185, dated August 29, 2008. The only change is the implementation date. All other material remains the same.

SUBJECT: Artificial Hearts

Effective Date: May 1, 2008
Implementation Date: December 1, 2008

I. GENERAL INFORMATION

A. Background: Medicare issued a national coverage determination (NCD) on May 1, 2008, that establishes limited coverage for artificial hearts under Coverage with Evidence Development (CED). Prior to May 1, 2008, the use of artificial hearts was not covered by Medicare as determined by the Centers for Medicare & Medicaid Services' (CMS') NCD effective May 19, 1986.

B. Policy: Medicare will cover artificial hearts when implanted in patients enrolled in clinical studies that have been approved by Medicare to meet all of the CED criteria. CMS will maintain a Web site (http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage) that will list all approved artificial heart studies. Coverage under CED will only apply to artificial hearts that are implanted in the context of one of the approved clinical studies listed on the above-noted Web site.

In addition, CMS has determined that since coverage is only available under clinical studies, the billing and coding requirements will be the same as what is currently used for other Medicare covered clinical trials under the Clinical Trials NCD effective 2007. This includes the current policy as it relates to Medicare managed care organizations in that they will not be responsible for payment for the artificial heart or for routine services related to the study until such time that the plans capitated rate has been appropriately adjusted to include them (see 42 CFR 422.109). Therefore, claims pertaining 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 fee-for-service contractor. 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.

Institutional claims for International Classification of Diseases, 9th edition (ICD-9) procedure code 37.52 are only payable when they include ICD-9 diagnosis code V70.7 (examination of participant in clinical research) and condition code 30 (qualifying clinical trial). The 8-digit National Clinical Trial Number is required (the trial number must match an approved trial).

Physician/Supplier claims for Common Procedural Terminology (CPT) code 0051T are only payable when they include ICD-9 diagnosis code V70.7 and HCPCS modifier Q0. As noted above, the 8-digit National Clinical Trial number is also required.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6185A.1	Effective for discharges on or after May 1, 2008, claims containing ICD-9 procedure code 37.52 shall only be paid when all the following are present: • Diagnosis code V70.7 (as secondary diagnosis) • Condition code 30 • Value Code D4 with an 8-digit clinical trial number that matches an approved clinical trial listed at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage	X		X			X			X	
6185A.2	Contractors shall reject claims with ICD-9 procedure code 37.52 that do not meet all the necessary billing criteria outlined in 6185A.1.	X		X			X			X	
6185A.2.1	Contractors shall use the following Claim Adjustment Reason Code (CARC) when ICD-9 procedure code 37.52 is present on a claim without all the required elements: **16** - Claim/service lacks information which is needed for adjudication.	X		X							
6185A.2.2	Contractors shall use the following Remittance Advice Remark Codes (RARCs) when applicable: For a missing/incomplete/invalid clinical trial number when ICD-9 procedure code 37.52 is billed, use the following RARC: **MA97** – Missing/ incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number. For a missing V70.7 diagnosis code when ICD-9 procedure code 37.52 is billed, use the following RARC: **M64** – Missing/incomplete/invalid other diagnosis. For a missing Condition code 30 when ICD-9 procedure code 37.52 is billed, use the following RARC: **M44** – Missing/incomplete/invalid condition code.	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6185A.2.3	Contractors shall use the following Medicare Summary Notice (MSN) when claims with ICD-9 procedure code 37.52 are rejected for not meeting the necessary billing requirements: **21.21** - This service was denied because Medicare only covers this service under certain circumstances. **21.21** - Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias.	X		X							
6185A.3	Effective for dates of service on or after May 1, 2008, claims containing CPT code 0051T shall only be paid when all the following are present: • Diagnosis code V70.7 (as primary diagnosis) • HCPCS modifier Q0 • An 8-digit clinical trial number that matches an approved clinical trial listed at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage **NOTE:** The HCPCS modifier Q0 must be on the same claim line as CPT code 0051T.	X			X			X		X	
6185A.4	Contractors shall return as unprocessable claims with CPT code 0051T that do not meet all the necessary billing criteria outlined in 6185A.3.	X			X						
6185A.4.1	Contractors shall 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.	X			X						
6185A.4.2	Contractors shall use 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 CPT code 0051T is present on a claim without the required diagnoses code or 8-digit clinical trial number.	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6185A.4.3	Contractors shall use the following RARCs when applicable: For a missing clinical trial number when CPT code 0051T is billed, use the following RARC: **MA97** – Missing/incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number. For a missing V70.7 diagnosis code when CPT code 0051T is billed, use the following RARC: **M64** – Missing/incomplete/invalid other diagnosis.	X			X						
6185A.4.4	Contractors shall use the following CARC when there is no HCPCS modifier Q0 appended to CPT code 0051T: **4** – The procedure code is inconsistent with the modifier used or a required modifier is missing	X			X						
6185A.4.5	Contractors shall use the following RARC when there is no HCPCS modifier Q0 appended to CPT code 0051T: **MA130** - 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.	X			X						
6185A.5	Contractors shall pay claims for beneficiaries enrolled in Medicare managed care plans for investigational and routine services provided as part of approved artificial heart clinical studies.	X		X	X		X	X		X	
6185A.6	Contractors shall establish a mechanism to hold claims outlined in 6185A.1 and 6185A.3 until the claims can be correctly processed.	X		X	X		X	X			
6185A.6.1	Contractors shall release and finalize any held claims upon successful implementation of this CR.	X			X						
6185A.6.2	Contractors shall pay interest as appropriate on held claims.	X		X	X		X	X			
6185A.7	Contractors shall release and finalize any held claims upon successful implementation of this CR and the FY 2009 Medicare Code Editor.	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6185A. 7.1	Contractors shall append condition code 15 to claims upon release to exempt them from CMS' claims processing timeliness standards.	X		X			X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6185A.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: JoAnna Baldwin at 410-786-7205 or joanna.baldwin@cms.hhs.gov
Institutional Claims Processing: Joe Bryson at 410-786-2986 or joseph.bryson@cms.hhs.gov
Practitioner Claims Processing: Vera Dillard at 410-786-6149 or vera.dillard@cms.hhs.gov

Post-Implementation Contact(s): Regional office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs):*
The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

80.3.2.1.3 - Carrier Specific Requirements for Certain Specialties/ Services

(Rev. 1592; Issued: 09-10-08; Effective Date: 05-01-08; Implementation Date: 12-01-08)

Carriers must return the following claim as unprocessable to the provider of service/supplier:

a. For chiropractor claims:

1. If the x-ray date is not entered in item 19 for claims with dates of service prior to January 1, 2000. Entry of an x-ray date is not required for claims with dates of service on or after January 1, 2000.

2. If the initial date "actual" treatment occurred is not entered in item 14. (Remark code MA122 is used.)

b. For certified registered nurse anesthetist (CRNA) and anesthesia assistant (AA) claims, if the CRNA or AA is employed by a group (such as a hospital, physician, or ASC) and the group's name, address, ZIP code, and PIN number, until the NPI is required, is not entered in item 33 or if the NPI is not entered in item 33a.of the Form CMS-1500 (8/05) when the NPI is required or, until the NPI is required, if their personal PIN is not entered in item 24K of the Form CMS-1500 (12-90) or if the NPI is not entered into item 24J of the Form CMS-1500 (8/05) when the NPI is required. (Remark code MA112 is used.)

c. For durable medical, orthotic, and prosthetic claims, if the name, address, and ZIP code of the location where the order was accepted were not entered in item 32. (Remark code MA 114 is used.)

d. For physicians who maintain dialysis patients and receive a monthly capitation payment:

1. If the physician is a member of a professional corporation, similar group, or clinic, and, until the NPI is required, the attending physician's PIN is not entered in item 24K of the Form CMS-1500 (12-90) or if the NPI is not entered into item 24J of the Form CMS-1500 (8/05) when the NPI is required). (Remark code N290 is used.)

2. If the name, address, and ZIP code of the facility other than the patient's home or physician's office involved with the patient's maintenance of care and training is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

e. For routine foot care claims, if the date the patient was last seen and the attending physician's PIN (or NPI when required) is not present in item 19. (Remark code N324 or N253 is used.)

f. For immunosuppressive drug claims, if a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist was used and their name is not present in items 17 or their UPIN (until the NPI is required) is not present in 17a. or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is required. (Remark code N264 or N286 is used.)

g. For all laboratory services, if the services of a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist are used and his or her name is not present in items 17 or their UPIN (until the NPI is required) is not present in 17a. or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is required. (Remark code N264 or N286 is used.)

h. For laboratory services performed by a participating hospital-leased laboratory or independent laboratory in a hospital, clinic, laboratory, or facility other the patient's home or physician's office (including services to a patient in an institution), if the name, address, and ZIP code of the location where services were performed is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

i. For independent laboratory claims:

1. Involving EKG tracing and the procurement of specimen(s) from a patient at home or in an institution, if the claim does not contain a validation from the prescribing physician that any laboratory service(s) performed were conducted at home or in an institution by entering the appropriate annotation in item 19 (i.e., "Homebound"). (Remark code MA116 is used.)

2. If the name, address, and ZIP code where the test was performed is not entered in item 32, if the services were performed in a location other than the patient's home or physician's office. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

j. For mammography "diagnostic" and "screening" claims, if a qualified screening center does not accurately enter their 6-digit, FDA-approved certification number in item 32 when billing the technical or global component. (Remark code MA128 is used.)

k. For parenteral and enteral nutrition claims, if the services of an ordering/referring physician, physician assistant, nurse practitioner, clinical nurse specialist are used and their name is not present in item 17 or their UPIN (until the NPI is required) is not present in item 17a. or if the NPI is not entered in item 17b.of the Form CMS-1500 (8/05) when the NPI is required). (Remark code N264 or N286 is used.)

l. For portable x-ray services claims, if the ordering physician, physician assistant, nurse practitioner, clinical nurse specialist's name, and/or UPIN (or NPI when required) is not entered in items 17 or their UPIN (until the NPI is required) is not entered in item 17a. or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is required). (Remark code N264 or N286 is used.)

m. For radiology and pathology claims for hospital inpatients, if the referring/ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist's name, if appropriate, is not entered in items or 17 or their UPIN (until the NPI is required) is not entered in item 17a. or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is required. (Remark code N264 or N286 is used.)

n. For outpatient physical or occupational therapy services provided by a qualified, independent physical, or occupational therapist, Medicare policy does not require the date last seen by a physician, or the UPIN or NPI, when required, of such physician. Medicare policy does not require identification of the ordering, referring or certifying physician on outpatient therapy claims, including speech-language pathology service claims. However, providers and suppliers are required to comply with applicable HIPAA ASC X12 837 claim completion requirements. See Pub. 100-04, chapter 5, §20 and Pub. 100-02, chapter 15, §§220 and 230 for therapy service policies. Deletion of this claim requirement for outpatient therapy services does not apply to the requirements for the date last seen and the UPIN or NPI, when required, of the ordering and supervising physician/nonphysician practitioner for therapy services provided incident to the services of a physician, because the incident to policies continue to require them.

1. If the UPIN (or NPI when required) of the attending physician is not present in item 19. (Remark code N253 is used.)

2. If the 6-digit (MM | DD | YY) or 8-digit (MM | DD | CCYY) date patient was last seen by the attending physician is not present in item 19. (Remark code N324 is used.)

o. For all laboratory work performed outside a physician's office, if the claim does not contain a name, address, and ZIP code, and PIN (until the NPI is required) where the laboratory services were performed in item 32 or if the NPI is not entered into item 32a. of the Form CMS-1500 (8/05) when the NPI is required), if the services were performed at a location other than the place of service home – 12. (Use Remark code MA114.)

p. For all physician office laboratory claims, if a 10-digit CLIA laboratory identification number is not present in item 23. This requirement applies to claims for services performed on or after January 1, 1998. (Remark code MA120 is used.)

q. For investigational devices billed in an FDA-approved clinical trial if an Investigational Device Exemption (IDE) number is not present in item 23, for dates of service through March 31, 2008. (Remark code MA50 is used.) With the use of new

modifier Q0, effective for dates of service on and after April 1, 2008, contractors will no longer be able to distinguish an IDE claim from other investigational clinical services. Therefore this edit will no longer apply.

r. For physicians performing care plan oversight services if the 6-digit Medicare provider number of the home health agency (HHA) or hospice is not present in item 23. (Remark code MA49 is used.)

s. For Competitive Acquisition Program drug and biological claims, in accordance with the instructions found in the Medicare Claims Processing Manual, chapter 17, section 100.2.1 – section 100.9.

t. For claims for artificial hearts covered by Medicare under an approved clinical trial, if procedure code 0051T is entered in Item 24D, and an 8-digit clinical trial number that matches an approved clinical trial listed at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/06_artificialhearts.asp#TopOfPage is not entered in Item 19; and the HCPCS modifier Q0 is not entered on the same line as the procedure code in Item 24D, and the diagnosis code V70.7 is not entered in Item 21 and linked to the same procedure code. (As appropriate, use remark code MA97 – Missing/ incomplete/invalid Medicare Managed Care Demonstration contract number or clinical trial registry number; M64 – Missing/incomplete/invalid other diagnosis; or claim adjustment reason code 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing.)

90.2.1 - Artificial Hearts and Related Devices

(Rev.1592 ; Issued: 09-10-08; Effective Date: 05-01-08; Implementation Date: 12-01-08)

Effective for discharges before May 1, 2008, Medicare does not cover the use of artificial hearts, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant (often referred to a "bridge to transplant").

Medicare does cover a Ventricular Assist Device (VAD). A VAD is used to assist a damaged or weakened heart in pumping blood. VADs are used as a bridge to a heart transplant, for support of blood circulation postcardiotomy or destination therapy. Refer to the NCD Manual, section 20.9 for coverage criteria.

The MCE creates a Limited Coverage edit for procedure code 37.66. This procedure code has limited coverage due to the stringent conditions that must be met by hospitals. Where this procedure code is identified by MCE, the FI shall determine if coverage criteria is met and override the MCE if appropriate.

Effective for discharges on or after May 1, 2008, the use of artificial hearts will be covered by Medicare under Coverage with Evidence Development when beneficiaries are enrolled in a clinical study that meets all of the criteria listed in Pub. 100-03, Medicare NCD Manual, section 20.9.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.1592 ; 09-10-08)

69.6 - Requirements *for Billing Routine Costs of* Clinical Trials

(Rev. 1592; Issued: 09-10-08; Effective Date: 05-01-08; Implementation Date: 12-01-08)

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service before January 1, 2008:

- HCPCS modifier 'QV'
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

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

- HCPCS modifier 'Q1' *(numeral 1 instead of the letter i)*
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to change request (CR) 5790 for more information regarding the 8-digit number. Below are the claim locators that providers should use to bill the 8-digit number:

- CMS-1500 paper form-place in Field 19 (preceded by 'CT')
- 837 P—Loop 2300, REF02, REF01-P4 (do not use 'CT' on the electronic claim).

Routine Costs Submitted by Institutional Providers

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code 'D4'---where the value code amount equals the *8*-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

NOTE: The QV/Q1 modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/Q1 modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/Q1 modifier will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

Inpatient Clinical Trial Claims

Institutional provider 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 Clinical Trial Claims

A) All services on the claim related to the trial - 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

B) Claim contains both services related and unrelated to the trial - 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*