CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1761	Date: June 26, 2009
	Change Request 6431

Transmittal 1743 is rescinded and replaced with Transmittal 1761, dated June 26, 2009. The Effective and Implementation dates have been changed to September 28, 2009. Also, in chapter 1, section 80.3.2.1.3, item p, which was erroneously deleted, has been restored. Additionally, in chapter 1, chapter 32, and Business Requirements 6431.1 and 6431.1.2, references to "90 days after issuance of CR 6431", have been replaced with "after September 28, 2009". All other material remains the same.

SUBJECT: Billing Routine Cost of Clinical Trials

I. SUMMARY OF CHANGES: CMS is eliminating the need for differentiation between a diagnostic clinical trial service and a therapeutic clinical trial service.

NEW / REVISED MATERIAL
EFFECTIVE DATE: ***For claims processed after September 28, 2009 with dates of service on or after January 1, 2008***
IMPLEMENTATION DATE: September 28, 2009

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	32/69/69.6/Requirements for Billing Routine Cost 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1761	Date: June 26, 2009	Change Request: 6431

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SUBJECT: Billing Routine Costs of Clinical Trials

Effective Date: ***For claims processed after September 28, 2009 with dates of service on or after January 1, 2008***
Implementation Date: ***September 28, 2009***

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) is clarifying that there no longer remains a need to make a distinction between a diagnostic versus therapeutic clinical trial service on the claim.

B. Policy: Contractors shall continue to report the ICD diagnosis code V70.7 on clinical trial claims.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

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	
6431.1	Effective for claims processed after *September 28, 2009*, of this CR, with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 shall be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.	X			X						
6431.1.1	Contractors shall return the following message: Claims adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the Remittance Advice Remark Code or NCPDP Reject Reason Code.) Remittance Advice Remark Code: M76. Missing/incomplete/invalid diagnosis or condition.	X			X						
6431.1.2	Effective for claims processed after *September 28, 2009,* of this CR, with dates of service on or after January 1, 2008, contractors shall disable any edits that pertain to clinical trial services being considered diagnostic versus therapeutic based on whether the diagnosis code V70.7 is submitted as the primary or secondary diagnosis.	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	
6431.2	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:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
None.	

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

V. CONTACTS

Pre-Implementation Contact(s):

Practitioner Claims Processing
Vera A. Dillard at 410 786-6149 or vera.dillard@cms.hhs.gov
Leslie Trazzi at 410 786-7544 or leslie.trazzi@cms.hhs.gov

Post-Implementation Contact(s): *Appropriate Project Officer or Contractor Manager*

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Intermediaries (RHHIs)*:

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.

69.6 - Requirements for Billing Routine Costs of Clinical Trials

(Rev.1761, Issued: 06-26-09, Effective Date: For claims processed after September 28, 2009, with dates of service on or after January 1, 2008; Implementation Date: September 28, 2009)

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 *secondary* diagnosis

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

- HCPCS modifier 'Q1' (numeral 1 instead of the letter i) *; and*
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the *secondary* 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 claims processed after September 28, 2009, with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 shall be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.

Contractors shall return the following messages:

Claims adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code.)

Remittance Advice Remark Code: M76, Missing/incomplete/invalid diagnosis or condition.

Effective for claim processed after September 28, 2009, with dates of service on or after January 1, 2008, contractors shall disable any edits that pertain to clinical trial services being considered diagnostic versus therapeutic based on whether the diagnosis code V70.7 is submitted as the primary or secondary diagnosis.

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') *; and*
- 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 providers billing clinical trial service(s) must report a secondary 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

On all outpatient clinical trial claims, providers need to do the following:

- *Report condition code 30,*
- *Report a secondary diagnosis code of V70.7; and*
- *Identify all lines that contain an investigational item/service with a HCPCS modifier of:*
    - *QA/QR for dates of service before 1/1/08; or*
    - *Q0 for dates of service on or after 1/1/08.*

- *Identify all lines that contain a routine service with a HCPCS modifier of:*
    - *QV for dates of service before 1/1/08; or*
    - *Q1 for dates of service on or after 1/1/08.*

80.3.2.1.3 - Carrier Specific Requirements for Certain Specialties/Services

(Rev.1761, Issued: 06-26-09, Effective Date: For claims processed after September 28, 2009, with dates of service on or after January 1, 2008; Implementation Date: September 28, 2009)

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.

3. When a diagnostic service is billed as a purchased service and the service is purchased from another billing jurisdiction, the billing provider must submit their own NPI in Item 32a with the name, address, and ZIP Code of the performing provider in Item 32. If Item 32 and 32a are not entered, remark code MA114 is used.

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.)

*u. For clinical trial claims processed **after September 28, 2009**, with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1, if the diagnosis code V70.7 is not submitted with the claim.*