CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2052	**Date: September 17, 2010**
	Change Request 6776

NOTE TO CONTRACTORS: TRANSMITTAL 1901, DATED JANUARY 29, 2010, IS RESCINDED AND REPLACED BY TRANSMITTAL 2052, DATED SEPTEMBER 17, 2010. THIS CR IS BEING REISSUED WITH A TECHNIAL CLARIFICATION TO THE HEALTHY CONTROL GROUP LANGUAGE CONTAINED IN PUB. 100-04, CHAPTER 32, SECTION 69.6. ALL OTHER INFORMATION REMAINS THE SAME.

Subject: Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial

I. SUMMARY OF CHANGES: Healthy Control Group Volunteers, by definition, do not have any underlying conditions. Therefore, providers need to report International Classification of Diseases, Ninth Edition Clinical Modification (ICD-9-CM) Diagnosis code, V70.7 (Examination of participant in clinical trial), as the primary diagnosis instead of the secondary diagnosis, as no primary diagnosis exists.

New / Revised Material
Effective Date: September 19, 2000
Implementation Date: July 6, 2010

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-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2052	Date: September 17, 2010	Change Request: 6776

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SUBJECT: Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial

Effective Date: September 19, 2000

Implementation Date: July 6, 2010

I. GENERAL INFORMATION

Background: Healthy Control Group Volunteers, by definition, do not have any underlying conditions. Therefore, providers need to report International Classification of Diseases, Ninth Edition Clinical Modification (ICD-9-CM) Diagnosis code, V70.7 (Examination of participant in clinical trial), as the primary diagnosis instead of the secondary diagnosis, as no primary diagnosis exists.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes 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	
6776.1	Contractors shall allow V70.7 as a primary diagnosis on clinical trial claims for dates of service on or after January 1, 2002.	X		X			X				
6776.2	Contractors shall allow V70.5 as a primary diagnosis on clinical trial claims for dates of service on or after September 19, 2000 through December 31, 2001.	X		X			X				
6776.3	The Integrated Outpatient Code Editor (IOCE) shall revise Edit 59 to look for the required V70.7 diagnosis code in both the primary and secondary diagnosis positions (instead of just the secondary position).										IOCE

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	

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	
6776.4	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							

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements:
"Should" denotes a recommendation.

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

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

V. CONTACTS

Pre-Implementation Contact(s): Joe Bryson at Joseph.Bryson@cms.hhs.gov or Valeri Ritter at Valeri.Ritter@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.

69.6 - Requirements for Billing Routine Costs of Clinical Trials

(Rev.2052, Issued: 09-17-10, Effective: 09-19-00, Implementation: 07-06-10)

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, *presumably provided to a participant in the healthy volunteer group. CMS covers costs of healthy volunteers in a qualified clinical trial if it meets the following conditions:*

- *The trial is not designed exclusively to test toxicity or disease pathophysiology.*
- *The trial must have therapeutic intent.*
- *If the trial has therapeutic interventions, it must enroll patients with diagnosed disease rather than healthy volunteers.*
- *If the trial is studying diagnostic interventions, it may enroll healthy patients in order to have a proper control group.*

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 diagnosis code *of* V70.*7 in the secondary position (or in the primary position if the patient is a healthy, control group volunteer)* 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 diagnosis code of V70.7 *in the secondary position (or in the primary position if the patient is a healthy, control group volunteer);* 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.

For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of this chapter.