CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 487 **Date: MARCH 4, 2005**

CHANGE REQUEST 3625

SUBJECT: Medicare Qualifying Clinical Trials

I. SUMMARY OF CHANGES: No change. This is a manualization of instructions in the MCM and previously issued PMs**.**

MANUALIZATION/CLARIFICATION – EFFECTIVE/IMPLEMENTATION DATES: Not Applicable.

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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 not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Chapter 32, Section 69.0 – Qualifying Clinical Trials

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 487	Date: March 4, 2005	Change Request 3625

SUBJECT: Medicare Qualifying Clinical Trials

I. GENERAL INFORMATION

A. Background:

CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine cost of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

B. Policy:

This is a manualization of instructions in MCM and previously issued PMs. There are no changes.

C. Provider Education: None.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3365.1	Contractors shall implement these previously issued requirements as outlined in previously issued CR 1424 & 1637, and Transmittal # 1770, dated September 18, 2002.	X		X						

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions
	N/A

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
	N/A

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: N/A **Implementation Date:** N/A **Pre-Implementation Contact(s):** Rhem Gray, (410) 786-6986 **Post-Implementation Contact(s):** Rhem Gray, (410) 786-6986	**Medicare Contractors shall implement these instructions within their current operating budgets.**

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

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 487, 03-04-05)

69.0 - Qualifying Clinical Trials
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

69.1 – General
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in ***all*** *clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in section 310.1 of the National Coverage Determinations Manual.*

69.2 - Payment for Qualifying Clinical Trial Services
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, DME fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

69.3 - Medical Records Documentation Requirements
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

69.4 - Local Medical Review Policy
(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

69.5 - Billing Requirements – General

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Instruct physicians, suppliers and hospitals to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free of charge by research sponsors may not be billed to Medicare.

69.6 - Billing Requirements for Dates of Service on or after January 1, 2002

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For services furnished on or after January 1, 2002, providers are required to submit the following information depending on the type of service and contractor (fiscal intermediary or carrier) to which they are billing:

Fiscal intermediary	***Carrier***
Condition code 30 (for all types of service)	*QV modifier*
ICD-9 diagnosis code V70.7 (as secondary diagnosis for all types of service)	*NOTE: Reporting of ICD-9 diagnosis code V70.7 is not required unless section 69.7 applies.*
QV modifier (outpatient types of services only)	

69.7 - Billing Requirements for Services Furnished to Healthy Control Group Volunteers Participating in Diagnostic Trials

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Routine costs submitted to carriers for services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed in the following manner:

- *The "QV" procedure code modifier is reported at the line item level.*
- *Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the **primary diagnosis***

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

Routine costs submitted to FIs for services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:

- *Condition code 30 (qualifying clinical trial) is reported at the line item level*
- *Diagnosis code V70.7 (*Examination of participant in clinical trial) is reported as the **secondary diagnosis**
- *"QV" procedure code modifier (only for outpatient claims submitted to FIs)*

Fiscal intermediary	***Carrier***
Condition code 30 (for all types of service)	*QV modifier*
ICD-9 diagnosis code V70.7 (as secondary diagnosis for all types of service)	*ICD-9 diagnosis code V70.7 (as primary diagnosis)*
QV modifier (outpatient types of services only)	

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If a service Medicare covers was billed with the appropriate clinical trial coding but was inadvertently denied (e.g., for medical necessity or utilization) and is subsequently brought to your attention, adjust the denied claim. If the denied services weren't properly coded as clinical trial services, instruct the provider to resubmit the service on a new claim with appropriate clinical trial coding.

69.9 - Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Providers who furnish covered clinical trial services to managed care beneficiaries must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill fee for service but have not enrolled with Medicare must contact their local carrier, intermediary, regional home health

intermediary or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare fee for service claims.

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for managed care enrollees when all services on the claim transaction record are coded as clinical trial services and the date(s) of service is (are) on or after September 19, 2000. In addition, CWF will not apply Part B deductible to clinical trial claims for managed care enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

69.11 - Resolution of CWF UR 5232 Rejects

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for a managed care enrollee, the entire claim will be rejected with the UR 5232 error code. When you receive a UR 5232 error code split the claim and resubmit the clinical trial portion to CWF. Process the non-clinical trial portion of the rejected claims in the same manner that other non-clinical trial fee for service claims for managed care enrollees are handled.