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# Medicare

## Carriers Manual

### Part 3 - Claims Process

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

Transmittal 1770

Date: SEPTEMBER 18, 2002

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Refer to: Change Requests 1424 & 1637

**HEADER SECTION NUMBERS**

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4906 – 4917

**PAGES TO INSERT**

4-4.5 – 4-.6 (2 pp.)  
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**PAGES TO DELETE**

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**NEW/REVISED MATERIAL--*EFFECTIVE DATE: Not applicable***  
***IMPLEMENTATION DATE: Not applicable***

**This transmittal manualizes carrier/DMERC claims processing instructions contained in Program Memoranda AB-01-130 and AB-01-142. Coverage instructions for clinical trials have been manualized in § 30-1 of the Coverage Issues Manual.**

Section 4906, General through Section 4917, Resolution of CWF UR 5232 Rejects, manualizes instructions previously released in Program Memoranda AB-01-130, dated September 19, 2001, and AB-01-142, dated October 2, 2001. These new sections provide instructions for coding and processing claims for Medicare qualifying clinical trial services, including fee for service claims for Medicare + Choice (M+C) enrollees.

**These instructions should be implemented within your current operating budget.**

## CHAPTER IV

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QUALIFYING CLINICAL TRIALS

4906. General--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 §30-1 of the Medicare Coverage Issues Manual.

4907. Payment for Qualifying Clinical Trial Services--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 Medicare + Choice (M+C) 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.

4908. Medical Records Documentation Requirements--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.

4909. Local Medical Review Policy--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.

4910. Billing Requirements—General--Instruct physicians and suppliers 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.

4911. Billing Requirements for Dates of Service on or after September 19, 2000 through December 31, 2001--For dates of service on or after September 19, 2000 through December 31, 2001, physicians and suppliers who bill you for services or items that meet the clinical trial coverage requirements outlined in the NCD must identify these services with the “QV” procedure code modifier. The modifier definition is: “Item or service provided as routine care in a Medicare qualifying clinical trial”. In addition, ICD-9-CM code V70.5 (“Health Examination of Defined Subpopulations”) must be shown as a secondary diagnosis on the claim.

The QV procedure code modifier plus the V70.5 diagnosis code 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 qualifying clinical trial and represents a routine cost of patient care, including the treatment of complications arising from participation in a qualifying clinical trial). Items and services that are provided solely to satisfy data collection and analysis needs and are not used in the clinical management of the patient are not covered and may not be billed/coded with the QV modifier. Do not pay for items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category even if billed with the QV modifier.

4912. Billing Requirements for Dates of Service on or after January 1, 2002--For services furnished on or after January 1, 2002, paper and electronic billers are to use procedure code modifier “QV” to identify and report services that constitute routine costs for qualifying clinical trials. The reporting of diagnosis code V70.5 as a secondary diagnosis is not required for Medicare qualifying clinical trial services furnished on or after January 1, 2002. For dates of service on or after January 1, 2002, the QV modifier constitutes the billers attestation that a service, supply or equipment meets the coverage criteria for qualifying clinical trial services processed by carriers and DMERCS.

4913. Billing Requirements for Services Furnished to Healthy Control Group Volunteers Participating in Diagnostic Trials--Routine costs 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 for applicable line items on paper and electronic claims.

If the QV modifier is billed and diagnosis code V70.7 is reported 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.

4914. Handling Erroneous Denials of Qualifying Clinical Trial Services--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.

4915. Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Medicare + Choice (M+C) Enrollees—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 (M+C plans. Providers who furnish covered clinical trial services to M+C 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 or National Supplier Clearinghouse, as appropriate, to complete an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in M+C 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 M+C enrollee claims are the same as those for regular Medicare fee for service claims.

4916. CWF Editing Of Clinical Trial Claims For M + C Enrollees --Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for M + C 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 M + C enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

4917. Resolution of CWF UR 5232 Rejects—If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for an M + C 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 M + C enrollees are handled. (See § 4267)