Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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CHANGE REQUEST 1424

SUBJECT: Revised Claims Processing Instructions for Medicare Qualifying Clinical Trial Claims for Managed Care (M+C) Enrollees

The purpose of this Program Memorandum (PM) is to provide contractors with revised instructions for processing Medicare qualifying fee-for-service clinical trial claims for managed care enrollees. Until Medicare capitation rates to M+C organizations are adjusted to account for clinical trials, Medicare contractors will pay providers on a fee-for-service basis for covered clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans.

For clinical trial bills for managed care enrollees to be paid, providers must report condition code 30, "Non-research Services Provided to a Patient Enrolled in a Qualified Clinical Trial" (effective with the 2001.2 systems release) and ICD-9 code V70.5 as the second or subsequent diagnosis code, (generally, the third or subsequent for HHAs). V70.5 cannot be reported as the principal diagnosis on Form HCFA-1450 or electronic equivalent submitted to intermediaries. The use of condition code 30 will not be recognized for managed care enrollee clinical trial claims processed prior to installation of the 2001.2 systems release.

For clinical trial claims of managed care enrollees billed as fee for service on Form HCFA-1500 or electronic equivalent, providers must include the "QV" procedure code modifier and ICD-9 code V70.5 in accordance with the M+C billing instructions in PM AB-00-89, Change Request 1241, dated September 19, 2000.

Clinical trial claims/services for managed care enrollees that are not coded accordingly will not be paid. Providers may resubmit clinical trial claims for managed care enrollees with the appropriate coding when such coding was omitted and caused the claim to be denied.

Determine payment for clinical trial services furnished to managed care (M+C) enrollees according to the applicable fee for service rules, except that managed care enrollees 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 clinical trial services paid under Medicare fee for service rules.

CWF Editing Of Clinical Trial Claims For Managed Care Enrollees – Carriers and DMERCs

Submit clinical trial services for managed care enrollees to CWF for payment approval. Effective with the 2001.2 systems release, CWF will no longer reject clinical trial claims for managed care enrollees (e.g., all services on a carrier claim transaction record are coded as clinical trial services). 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).

Carrier and DMERC Resolution of UR 5232 CWF Rejects

When you send a claim transaction to CWF that includes both clinical trial and non-clinical trial services, the entire claim will be rejected with the UR 5232 error code. When the UR 5232 error code is received on such claims, split the claim and resubmit the clinical trial portion to CWF.

Process the non-clinical trial portion of the rejected claim in the normal manner that any other fee for service claim for a managed care enrollee is handled.

Until CWF changes in the 2001.2 systems release are installed, make user controlled changes if possible to set the HMO override field to 1 (field 21 on the HUBC/HUDC record) based on the presence of a QV modifier and diagnosis code V70.5, and resubmit rejected clinical trial services to CWF. However, this override action may result in the application of the Part B deductible by CWF until the 2001.2 systems release is installed. If the deductible is applied to a clinical trial claim for a managed care enrollee, the claim must be adjusted once CWF changes have been made. Develop a method for identifying such claims for retrieval and adjustment action subsequent to the installation of the 2001.2 systems release.

Educate appropriate contractor staff regarding this deductible application problem for managed care enrollee claims so that they are aware of this situation when interacting with beneficiaries and providers who may question why the deductible was applied.

NOTE: If this override procedure requires standard system changes to implement (i.e., it is not a user controlled function), the system maintainer must obtain HCFA prior approval through its designated maintenance contact person before making any system changes. Otherwise, continue paying these CWF rejected claims outside the system until the 20001.2 systems release is installed.

Payment and Standard Systems and CWF Editing of Clinical Trial Claims for Managed Care Enrollees – Intermediaries and RHHIs

Effective with the implementation of the 2001.2 systems release, CWF and standard systems will accept and approve payment bills for clinical trials containing condition code 30 for M+C enrollees. This condition code is the identifier used by the standard systems and CWF to bypass CWF reject condition UR 5233, and the application of the deductible for managed care beneficiaries. Specifically, outpatient bills for clinical trials with dates of service on or after September 19, 2000, and inpatient bills with discharges on or after September 19, 2000, can be paid through the normal claims process once the 2001.2 systems release is installed.

Contractors must resubmit previously processed clinical trail claims paid outside the system for M+C enrollees (i.e., claims having ICD-9 code V70.5 that received CWF reject code UR 5233) to CWF. Once the 2001.2 systems release is installed, you must include condition code 30 when resubmitting these clinical trial claims to CWF.

CWF will not apply Part A or Part B deductible to clinical trial claims for M+C enrollees (i.e., CWF will process clinical trial services for M+C enrollees as if the Part A and Part B deductibles have already been met).

Providers should only submit clinical trial claims for managed care enrollees to you. Services not defined as routine costs of clinical trials should be billed separately and directly to the M+C organization. However, when an inpatient stay contains a mix of clinical trial services and other services needed as a result of the patient's underlying medical condition, providers should not attempt to separate these services. Instead, they should send the entire inpatient claim to you rather than bill the M+C organization.

Because payment for clinical trial services for M+C enrollees will be made on a fee-for-service basis using original Medicare payment amounts, any indirect medical education (IME) payments that hospitals would ordinarily receive will be included in these payment amounts. Therefore, M+C enrollee providers should not submit IME-only bills to you or M+COs.

Billing Requirements for Intermediaries

Follow the general review instructions in §3604 of the Medicare Intermediary Manual, Part 3. The provider bills you on Form HCFA-1450, or electronic equivalent.

All applicable bill types (inpatient and outpatient) are applicable.

For M+C enrollees, providers must report condition code 30 in Form Locator (FLs) 24-30, "Condition Codes." In addition, providers report ICD-9 code V70.5 (Health Examination of Defined Subpopulations) as the second or subsequent diagnosis code (generally, the third or subsequent for HHAs), in FLs 68-75, "Other Diagnoses Codes", V70.5 cannot be reported as the principal diagnosis.

Contractor Submission of Claims for Clinical Trial Services Paid Outside of CWF (All Contractors)

It will be necessary to submit claim transactions to CWF for clinical trial services that you pay outside of the system once the 2001.2 systems release has been installed. You will need to adjust your internal claim history to reflect any administrative payments made outside the system and submit a transaction to post the paid claim to CWF history. Your system will also need to be modified to insure that a duplicate payment is not generated for services paid outside the system when you receive approval of the transaction from CWF.

The *effective date* for this PM is September 19, 2000.

The *implementation date* for this PM is April 2, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 2, 2002.

If you have any questions, please submit them via E-mail to clinicaltrials@HCFA.GOV.