CMS Manual System

Pub. 100-16 Medicare Managed Care

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

Transmittal: 57 **Date: AUGUST 13, 2004**

I. SUMMARY OF CHANGES:

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 13, 2004

Table of Contents - Added new line for new Exhibit 30.

Section 55 - Coverage of Clinical Trials:

In first paragraph, updated years "2002 through 2003" to read "2002 through 2005."

In second paragraph, updated reference to the Medicare National Coverage Determinations manual and the web address.

Deleted previously fourth and fifth paragraphs regarding payment of clinical trail items and services on a fee-for-fee service basis.

Added fifth paragraph referring reader to Exhibit 2, the Medicare National Coverage Determinations Manual, and Program Memorandum AB-01-142 for information on billing for clinical trial services.

Deleted the previously last two paragraphs which together provided reference to Program Memorandum and instructions on submitting claims for clinical trail services.

Miscellaneous changes throughout section.

Section 111.1 - Hospital Inpatient Data - Updated citation in last sentence to read "Exhibit 30" for new exhibit instead of "the section of these instructions titled Coexisting Conditions."

Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks - Added new exhibit.

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 only receive the new/revised information 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
R	7 / Table of Contents
R	7 / 55 / Coverage of Clinical Trials
R	7 / 111 / 111.1/ Hospital Inpatient Data
N	7 / Exhibits / Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks

III. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Special Notification

Medicare Managed Care Manual

Chapter 7 - Payment to Medicare + Choice (M+C) Organizations

Last Updated - Rev. 57, 08-13-04

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55 - Coverage of Clinical Trials

(Rev. 57, 08-13-04)

For Calendar Years (CY) 2002 *through 2005*, CMS will continue the CY 2001 policy of making payments on a fee-for-service *basis* for covered clinical trial costs *for M+C enrollees*.

On September 19, 2000, the Centers for Medicare & Medicaid Services (CMS) published a National Coverage Determination (NCD) regarding coverage of certain benefits related to clinical trials that were not covered by Medicare prior to that date. (See *§310.1* of the *Medicare National Coverage Determinations* Manual at *http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103c01.pdf*. Since the cost of covering these new benefits was not included in the 2001 M+C capitated payment rates, and since this cost met the threshold for "significant cost" under 42 CFR 422.109(*a*), Medicare paid for covered clinical trial services outside of the M+C capitated payment rate through CY 2001. Medicare intermediaries and carriers made payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

We reviewed the M+C payment rates for CY 2002, which were published on March 1, 2001, and determined that these rates *did* not reflect any adjustment for this significant cost NCD. We determined, therefore, that the published CY 2002 rates *did* not adjust appropriately for the costs of this NCD, as required under §1853(c)(7) of the Social Security Act (the Act). *F*or CY*s* 2002 *through 2005*, CMS continue*s* the CY 2001 policy of making payments on a fee-for-service basis for covered clinical trial *items and services provided M+C enrollees*. Medicare intermediaries and carriers will make payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

In CY 2001, original Medicare cost-sharing amounts applied automatically to clinical trial services covered by the NCD because they were covered "outside" the M+C contract. For CY*s* 2002 *through 2005*, however, these services are now considered part of the M+C plan, even though CMS is continuing to pay for them on a fee-for-service basis. Thus, M+C organizations have the flexibility to adopt *original Medicare cost-sharing amounts or adopt* their own cost-sharing structures for these services (even though CMS' payment will be based on the original Medicare rules).

See Exhibit 2 for further information. Section 310.1 of the Medicare National Coverage Determinations Manual, available at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103c01.pdf, and Program Memorandum AB-01-142, available at http://www.cms.hhs.gov/manuals/pm_trans/AB01142.pdf, give instructions to providers and suppliers on billing intermediaries and carriers for clinical trial services.

111.1 - Hospital Inpatient Data

(Rev. 57, 08-13-04)

Inpatient hospital data should be differentiated based on whether it is received from within or outside of the M+C organization's provider network. Per 42 CFR 422.204(a)3(i) all M+C organization network hospitals must have a Medicare provider agreement; by extension, a network provider should have a Medicare provider billing number for a hospital inpatient facility. If a facility does not have a hospital inpatient Medicare provider number, the M+C organization shall not submit diagnoses from that facility as hospital inpatient data. Please note that it is not necessary for M+C organizations to receive the Medicare provider number from the hospital on incoming transactions, i.e., the M+C organization may utilize its own provider identifications system. Regardless of how M+C organizations identify their facilities, M+C organizations must be able to distinguish diagnoses submitted by facilities that qualify as Medicare hospital inpatient facilities from diagnoses submitted by non-qualifying facilities.

For diagnoses received from non-network facilities, the M+C organization should first check whether the hospital is a Medicare-certified hospital inpatient facility. If the provider is a Medicare-certified hospital inpatient facility, the M+C organization should submit the diagnoses from this facility. If the hospital is not Medicare-certified, but is a Department of Veterans Affairs (VA) or DoD facility, the M+C organization must verify that it is a legitimate inpatient facility by contacting the Customer Service and Support Center (CSSC) prior to submitting data from that facility. If the hospital is not Medicare-certified or VA/DoD, the M+C organization should contact CMS to verify that the facility qualifies as a hospital inpatient facility prior to submitting any diagnoses from that facility.

To aid in determining whether or not a provider is a Medicare-certified hospital inpatient facility, the M+C organization may refer to the Medicare provider number. The Medicare provider number has a two-digit state code followed by four digits that identify the type of provider and the specific provider number. Exhibit 25 outlines the number ranges for all facility types that CMS considers to be Medicare hospital inpatient facilities. If the facility's Medicare provider number is unknown, the M+C organization may verify the provider number with the facility's billing department.

Some hospitals also operate Skilled Nursing Facilities (SNFs) as separate components within the hospital or have components with "swing beds" that can be used for either hospital inpatient or SNF stays. The M+C organizations shall not submit any diagnoses for stays in the SNF component of a hospital or from swing bed stays when the swing beds were utilized as SNF beds. Stays in both of these circumstances qualify as SNF stays and do not qualify as hospital inpatient stays. If the Medicare provider number is on the incoming transaction from the facility, the M+C organization may distinguish the SNF or SNF swing-bed stays by the presence of a U, W, Y, or Z in the third position of the Medicare provider number (e.g., 11U001).

Principal Hospital Inpatient and Other Hospital Inpatient Diagnoses

The M+C organizations must differentiate between the principal hospital inpatient diagnosis and all other hospital inpatient diagnoses when coding the provider type on the risk adjustment transaction. According to the Official ICD-9 CM Guidelines for Coding and Reporting, the principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." The principal diagnosis as reported by the hospital shall be coded as Provider Type 01, Principal Hospital Inpatient. The CMS strongly recommends that M+C organizations continue to collect electronic encounter data or claims from hospital inpatient stays to ensure the proper identification of the principal diagnosis.

The remaining diagnoses from a hospital inpatient stay shall be coded as Provider Type 02, Other Hospital Inpatient. The guidance for coding other conditions appears in Official ICD-9 CM Guidelines for Coding and Reporting, as well as in *Exhibit 30*.

Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks

(Rev. 57, 08-13-04)

Medicare utilizes ICD-9-CM as the official diagnosis code set for all lines of business. The "Official ICD-9 CM Guidelines for Coding and Reporting" provides guidance on diagnosis coding. This document provides guidelines for hospital inpatient, hospital outpatient and physician services. In accordance with this policy, CMS will utilize ICD-9

diagnosis codes in the determination of risk adjustment factors. M+C organizations must submit for each beneficiary all relevant ICD-9 codes that are utilized in the risk adjustment model. M+C organizations must submit each relevant diagnosis at least once during a risk adjustment data reporting period, with the first period being July 1, 2002 – June 30, 2003. See http://www.cms.hhs.gov/paymentsystems/icd9/default.asp for information regarding ICD-9-CM codes.

At a minimum, the submitted ICD-9 codes must be sufficiently specific to allow appropriate grouping of the diagnoses in the risk adjustment model. For the complete list of diagnoses used in the risk adjustment model, as well as the list of minimal ICD-9 codes required to group diagnoses for risk adjustment, see http://www.cms.hhs.gov/healthplans/riskadj/. In all cases, coding to the highest degree of specificity provides the most accurate coding and ensures appropriate grouping in the risk adjustment model.

M+C organizations must apply the following guidelines when collecting data from their provider networks. If the M+C organization utilizes an abbreviated method of collecting diagnoses, such as a superbill, the diagnoses may be coded to the highest level of specificity or to the level of specificity necessary to group the diagnosis appropriately for risk adjusted payments. If the M+C organization collects data using an encounter or claim format, the codes should already be at the highest level of specificity. CMS encourages M+C organizations to utilize the full level of specificity in submitting risk adjustment data. Regardless of the level of specificity of submitted diagnoses, a medical record must substantiate all diagnostic information provided to CMS.

Coexisting Conditions

Physicians and providers should use the "Official ICD –9-CM Guidelines for Coding and Reporting" (found at http://www.cms.hhs.gov/paymentsystems/icd9/default.asp) and Medicare fee-for-service rules when submitting risk adjustment data to M+C organizations. The official guidelines that govern those coexisting conditions that may be coded and reported by hospital inpatient, hospital outpatient and physician providers are summarized below. The guidelines for inpatient hospital stays are as follows:

> *"…all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded."*

The guidelines for coexisting conditions that should be coded for hospital outpatient and physician services are as follows:

> *"Code all documented conditions that coexist at time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19) may be used as secondary*

codes if the historical condition or family history has an impact on current care or influences treatment."

Physicians and hospital outpatient departments shall not code diagnoses documented as "probable," "suspected," "questionable," "rule out," or "working" diagnosis. Rather, physicians and hospital outpatient departments shall code the condition(s) to the highest degree of certainty for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit.
