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TRICARE
MANAGEMENT ACTIVITY

PCPB

CHANGE 59
6010.51-M
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PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE OPERATIONS MANUAL (TOM)

The TRICARE Management Activity has authorized the following addition(s)/
revision(s) to 6010.51-M, reissued August 2002.

CHANGE TITLE: CANCER CLINICAL TRIALS

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): This change will implement the cancer clinical trials
benefit under TRICARE and terminate the Department of Defense Cancer Prevention
and Treatment Clinical Trials Demonstration for new participants.

EFFECTIVE AND IMPLEMENTATION DATE: April 1, 2008

This change is made in conjunction with Aug 2002 TPM, Change No. 71, and Aug
2002 TSM, Change No. 54.

Laura Sells
Chief, Purchased Care Procurement Branch

ATTACHMENT(S): 8 PAGES
DISTRIBUTION: 6010.51-M

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT

CHANGE 59
6010.51-M
February 25, 2008

REMOVE PAGE(S)

CHAPTER 3

Section 4, pages 1 and 2

CHAPTER 20

Section 2, pages 3 through 8

INSERT PAGE(S)

Section 4, pages 1 and 2

Section 2, pages 3 through 8

NON-TED VOUCHERS

1.0. GENERAL

Non-*TRICARE Encounter Data (TED)* vouchers (like TED vouchers) are used by the contractor to request *TRICARE Management Activity (TMA)*, *Contract Resource Management (CRM)* payment authorization against their bank accounts. Non-TED vouchers are required because the data associated with these types of transactions is incompatible with the data formats used by the TED system. Listed below are types of non-TED vouchers:

1.1. Capital And Direct Medical Education Costs (CAP/DME)

These are annual payments made by the contractor from the non-financially underwritten bank account to hospitals requesting reimbursement under the TRICARE/CHAMPUS *Diagnostic Related Group (DRG)*-Based Payment System (excludes children's hospitals). Payments will be computed based on the TRICARE Reimbursement Manual (*TRM*), Chapter 6, Section 8.

1.2. Demonstrations

These are trial programs designed to see if changes in benefits or financing methods improves beneficiary satisfaction and/or reduces costs to the government. These demonstrations may be geographically specific, contractor specific or may vary in many ways from TRICARE Standard benefits. The data associated with these projects may be incompatible with TED data formats and may require separate voucher reporting of non-financially underwritten bank account transactions. Cancer Clinical Trials *under the demonstration* will be reported as a TEDs voucher, see Chapter 3, Section 3.

2.0. COMPUTATION OF PAYMENTS

Each type of voucher (i.e., CAP/DME, etc.) shall be processed and reported separately. The contractor shall compute the amount due for each beneficiary based on the procedures specified in the *TRICARE Operations Manual (TOM)* or TRM for that particular program. The contractor shall group each type of voucher by program, prepare and send an electronic data submission to TMA, CRM for approval and release of payments. (See Chapter 3, Addendum A, Figure 3-A-8 for CAP/DME electronic format.)

3.0. APPROVAL AND RELEASE OF PAYMENTS

Approval and release of payments shall be done in accordance with the procedures defined in Chapter 3, Section 2, paragraph 5.0.

4.0. CHECK REPORTING REQUIREMENTS

Check reporting shall be done in accordance with procedures defined in [Chapter 3, Section 2, paragraph 8.0](#).

- 3.2.3.** The patient continues to meet entry criteria for said protocol; and
- 3.2.4.** The institutional and individual providers are TRICARE-authorized providers.
- 3.3.** The DoD will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials. *Costs associated with non-treatment research activities may include administrative costs, such as, record keeping costs, publication costs, etc.*
- 3.4.** Cost-shares and deductibles applicable to TRICARE also apply under this Demonstration. For TRICARE Prime enrollees, including those enrolled in *Uniformed Services Family Health Plan (USFHP)*, applicable co-pays apply.

NOTE: Those patients enrolled in the previous breast cancer demonstration prior to January 1, 1996 (the effective date of the expanded cancer demonstration), will continue to have cost-shares and deductibles waived through the completion of their protocol. Waiver of the cost-shares and deductibles apply regardless of whether they were randomized to the experimental or conventional arm of the protocol.

3.5. The Assistant Secretary of Defense (Health Affairs) originally approved this DoD demonstration for a period of one year (January 1, 1996 - December 31, 1996). The demonstration has been extended until such time the Interagency Agreement between DoD and the National Cancer Institute (NCI) *dated June 21, 1999*, is terminated.

3.6. Retroactive authorizations can be authorized in accordance with the provisions outlined in [32 CFR 199.4\(g\)\(19\)](#). *retroactive authorization for coverage of a cancer clinical trial can be issued to those beneficiaries who began participation in such trial before termination of the cancer demo. Such retroactive authorization for coverage under the cancer demo rules can be issued even after termination of the demo.*

3.7. *The demonstration will expire on March 31, 2008. Requirements of this chapter as related to cancer demonstration cease at 12:00 midnight on March 31, 2008, except for claims for demonstration enrollees whose treatment is in progress when the demonstration expires. The demonstration retains responsibility for these claims until the beneficiary is discharged from the cancer clinical trial. For cancer clinical trials benefit, see TRICARE Policy Manual (TPM), Chapter 7, Section 24.1.*

3.8. *The records management requirements described in Chapter 2 apply to cancer demonstration records.*

4.0. APPLICABILITY

4.1. The Demonstration applies to all TRICARE-eligible beneficiaries. Active duty members continue to be eligible for direct care system services. The demonstration does not apply to Continued Health Care Benefit Program (CHCBP) enrollees.

4.2. Since demonstration benefits are not the same as TRICARE benefits, all inquiries and claims related to the Demonstration, including claims for conventional therapy under Phase III protocols shall be submitted to the appropriate contractor, referencing the Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration.

4.3. Since the DoD has no authority regarding the NCI protocol eligibility for the sponsored study, if a patient does not meet the criteria for enrollment, appeal rights do not apply.

5.0. GENERAL DESCRIPTION OF ADMINISTRATIVE PROCESS

5.1. The attending oncologist or physician shall determine the eligible patient's needs and consult with the contractor/NCI to determine which, if any, Phase II or Phase III, NCI-sponsored studies are appropriate for the patient.

5.2. Following the identification of an appropriate sponsored study within the terms of the Demonstration, the attending oncologist or physician shall apply for Demonstration benefits to the case manager's office specially designated at the contractor.

5.3. Following a validation of the eligibilities of the patient and the sponsored study under the terms of the Demonstration, the contractor shall issue a written decision to both the patient and the applicant provider.

5.4. All claims for approved care under the Demonstration shall be submitted to the contractor for adjudication.

6.0. TMA AND CONTRACTOR RESPONSIBILITIES

6.1. TMA will provide:

6.1.1. Demonstrations will be non-financially underwritten transactions and follow vouchering rules in [Chapter 3, Section 3](#) through [5](#).

6.1.2. Case management and claims adjudication functions via specific contractual arrangement(s) with one or more Demonstration claims processors.

6.1.3. Periodic review and evaluation of the Demonstration claims adjudication process.

6.1.4. Specific written guidance to the Demonstration claims processor(s) regarding case management services and claims adjudication services to be provided by the claims processor under the terms of the Demonstration.

6.1.5. Public affairs functions to properly inform and periodically update the patient and provider communities regarding the terms of the Demonstration.

6.2. The contractor shall:

6.2.1. Provide a registered nurse to serve as case manager for inquiries and actions pertinent to the Demonstration.

6.2.2. Ensure the provider has submitted a letter on the facility's letterhead certifying:

6.2.2.1. The protocol is an NCI sponsored study; and

- 6.2.2.2.** The index patient meets all entry criteria for said protocol; and
- 6.2.2.3.** Notification will be provided to the contractor's Demonstration case manager of the patient's registration date when treatment actually begins; and
- 6.2.2.4.** Notification will be provided to the contractor's Demonstration case manager if the patient becomes ineligible for the study prior to treatment.
- 6.2.3.** Verify the letter from the facility includes the patient's name, sponsor's SSN, the title and phase of the protocol and the NCI number of the protocol and/or other appropriate evidence of NCI sponsorship.
- 6.2.4.** Subscribe to the NCI's Comprehensive Cancer Database known as the Physician's Data Query (PDQ), to assist in determining whether a particular study meets the requirements of the Demonstration and whether the patient is eligible for a particular protocol. For those studies that are not listed on the PDQ, the contractor will work with NCI staff to verify NCI sponsorship.
- 6.2.4.1.** Unlike the other NCI sponsorship categories listed in [paragraph 3.1.](#) under Policy, protocols for Cancer Center Studies are not individually reviewed by the NCI. Instead, the NCI designates specific institutions as meeting NCI criteria for clinical and comprehensive cancer centers. Cancer center protocols receive approval through an NCI approved institutional peer review and quality control system at the institution. Protocols which have been through this process receive formal notification of approval from The Clinical Protocol Review and Monitoring Committee and, therefore, are considered NCI sponsored, but may not appear in the PDQ. A provider who is seeking to enter a patient into a Cancer Center Study must provide evidence of NCI sponsorship by forwarding the formal notification of approval from this specific committee. Formal notification of approval by the Clinical Protocol Review and Monitoring Committee will be required for approval of treatment in Cancer Center Studies which are not otherwise sponsored through the CTEP program, NCI cooperative groups, or NCI grants.
- 6.2.4.2.** Certain protocols listed in the PDQ may not be clearly identified in terms of NCI sponsorship. Clinical trials conducted as part of an NCI grant, or those identified with a "V" number, must be verified for NCI sponsorship with the NCI project officer. Physicians who are holders of the grant at the institution must provide written clarification that the proposed treatment is a protocol under their NCI grant. The grant title and number must be specified.
- 6.2.4.3.** Requests for treatment in clinical trials overseas must be verified as to NCI sponsorship with the NCI project officer.
- 6.2.4.4.** Protocols that are co-sponsored by the NCI and other Federal Agencies must be verified by the NCI project officer.
- 6.2.5.** Verify the patient's eligibility on the Defense Enrollment Eligibility Reporting System (DEERS).

6.2.5.1. If the patient is authorized to receive the care under the Demonstration, but DEERS reflects that the patient is not eligible, a statement shall be added to the authorization letter indicating before benefits can be paid, the patient must be listed as eligible on DEERS.

6.2.5.2. The patient shall be referred to the pass/ID card section of the military installation nearest their home for an eligibility determination.

6.2.5.3. If a patient is listed on DEERS as being eligible as of the date the cancer therapy begins, all services provided as a result of participation in an NCI sponsored study shall be covered. This also applies to patients whose treatment is in progress when the Demonstration expires.

6.2.6. Issue an authorization ([Figure 20-2-2](#)) or denial ([Figure 20-2-3](#)) letter to the applicant provider and patient once a determination is made regarding a particular protocol.

6.2.7. Establish and maintain a database of patients participating in the Demonstration. The database shall include the patient's name, sponsor's social security number, name and number of protocol, type of cancer, hospital name and address and total cost.

6.2.8. Furnish a list of enrollees in the Demonstration to the contractor's Program Integrity Unit with instructions to run an annual post-payment report to determine if hospitals are receiving additional unlawful payments as a result of also receiving payment under TRICARE. If such payment exists, it shall be the responsibility of the contractor to initiate recoupment action for any Demonstration benefits paid in error. This function will be supervised by the TMA Program Integrity Office.

6.2.9. Complete a semiannual report outlining the number of TRICARE patients enrolled in each protocol and the outcome. The report shall indicate the date the TRICARE beneficiary was accepted into the protocol and the patient shall be carried on the report until the Demonstration ends. The report shall also include a list of patients who were denied enrollment and the reason for each denial. The report shall be completed on March 1 and September 1 of each year and sent to the MHSO, Program Development, TRICARE Management Activity.

6.3. The contractor may at its discretion establish a dedicated toll-free telephone number to receive inquiries from both patients and providers regarding the Demonstration. If a dedicated toll-free telephone number is established for this demonstration, the phone shall be staffed seven hours a day during normal business hours. In the absence of a dedicated toll-free number for Demonstration inquiries, contractors shall use their primary toll-free telephone inquiry system (see the TRICARE Operations Manual, [Chapter 12, Section 7](#) and [Chapter 22, Section 4](#)).

6.4. The contractor may at its discretion establish a dedicated mailing address where Demonstration inquiries and claims shall be sent for expedited response and/or claims adjudication. In the absence of a dedicated mailing address for Demonstration inquiries and claims, contractors shall use their primary address(es) for written correspondence and claims (see the TRICARE Operations Manual, [Chapter 12, Section 5](#), [Chapter 12, Section 6](#), and [Chapter 22, Section 4](#)).

7.0. CLAIMS PROCESSING REQUIREMENTS

7.1. Verify TRICARE-eligibility on the DEERS prior to payment.

7.2. Both institutional and professional charges shall be reimbursed based on billed charges.

7.2.1. The cancer center shall submit all charges on the basis of fully itemized bills. Each service and supply shall be individually identified and submitted on the appropriate claim forms.

7.2.2. All claims for medical care required as a result of participation in an NCI sponsored study for cancer prevention or treatment that is not a TRICARE benefit, shall be processed and paid under the demonstration.

7.3. Cost-shares and deductibles applicable to TRICARE will also apply under the Demonstration. For TRICARE Prime enrollees, including those enrolled in USFHP, applicable co-pays will apply.

7.3.1. The contractor shall query the DEERS Catastrophic Cap and Deductible Data (CCDD) to determine the status of deductible and catastrophic cap met amounts for TRICARE-eligible beneficiaries at the time the costs are listed on the voucher for processing and payment.

7.3.2. The contractor shall determine what expenses to apply to the deductible and catastrophic cap and reports these to the CCDD. These expenses shall be reported at the same time the costs are listed on the voucher for processing, prior to payment of the claim.

7.3.3. The contractor shall use query type 80. Type 80 (nonclaim update) is used to request crediting of amounts since this is a manual process.

7.4. Double coverage provisions apply. Acceptable evidence of processing by the double coverage plan is outlined in TRICARE Reimbursement Manual, [Chapter 4](#). In double coverage situations, the Demonstration shall pay the balance after the other health insurance has paid.

7.5. Claims for this demonstration will be paid from the applicable non-underwritten bank accounts (see [Chapter 3](#)), and submitted through normal TEDS processing as required in the TRICARE Systems Manual with the applicable coding for clinical trials *demonstration with enrollment effective before April 1, 2008*.

7.6. Claims for this demonstration may be submitted either by EMC, through the dedicated demonstration mailing address, or through the appropriate regional claims processing address(es).

FIGURE 20-2-1 SAMPLE OF AUTHORIZATION LETTER TO BE ISSUED TO INSTITUTION VERIFYING TRICARE ELIGIBILITY FOR SAID PATIENT TO BE ENROLLED IN NCI SPONSORED STUDIES

Hospital Name
Street Address
City, ST ZIP

Dear _____:

This responds to your request for TRICARE eligibility verification, prior to enrollment of a TRICARE beneficiary in an NCI sponsored study for the prevention/treatment of cancer.

This is to inform you the following patient is eligible for TRICARE benefits and may be considered for enrollment in the NCI sponsored study. Enrollment in the study is a voluntary decision and can be made only by the patient.

Name of Patient: _____

Sponsor's Social Security Number: _____

If you have any questions or concerns, you may contact me at the address in the letterhead.

Sincerely,

Title

Enclosure