

DEPARTMENT OF DEFENSE CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION

1.0. PURPOSE

The purpose of this demonstration is to improve TRICARE-eligible family member access to promising new cancer therapies, assist in meeting the National Cancer Institute's (NCI) clinical trial goals, and to assist in the formulation of conclusions regarding the safety and efficacy of emerging therapies in the prevention and treatment of cancer. The DoD's financing of these sponsored studies will include Phase II and Phase III protocols approved under the NCI for all types of cancer.

2.0. BACKGROUND

2.1. On November 16, 1998 (Vol 63, No. 220) the Federal Register announced the one year extension of a demonstration project in which the DoD provides TRICARE reimbursement for eligible beneficiaries who receive cancer treatment under approved National Cancer Institute clinical trials. A Federal Register Notice was published on January 5, 2000, extending the DoD Cancer Prevention and Treatment Clinical Trials Demonstration until such time the Interagency Agreement between DoD and the National Cancer Institute (NCI) is terminated. Extending the demonstration will allow for an evaluation of costs associated with this demonstration project.

2.2. The National Cancer Institute (NCI) sponsors and actively coordinates an extensive clinical trials program for the evaluation of prevention, early detection, treatment, and supportive care for various types of cancer. The NCI's program includes sponsorship of studies in single institutions, as well as large, multi-center, randomized trials in cooperative networks. The trials encompass studies of cancers occurring in virtually all anatomical sites and in all stages of development. The NCI clinical trials program has been the means by which the oncology community has developed most of the formal clinical evidence for the efficacy of the various prevention, early detection, and management approaches in clinical cancer.

2.3. Approximately 11,760 TRICARE-eligible patients are diagnosed with some form of cancer each year, based on age adjusted incidence rates. Recognizing that some individuals participating in Phase III trials would be randomized for conventional treatment as part of a control group, the number of patients receiving treatment under NCI-sponsored Phase II or Phase III clinical trials is estimated to be about 350. The number may grow as awareness of the demonstration increases, thereby increasing the potential pool of patients meeting protocol eligibility requirements.

2.4. In support of NCI's efforts to further the science of cancer treatment, the Department expanded its breast cancer demonstration to include all NCI-sponsored Phase II and Phase III clinical trials. This expanded demonstration will enhance current NCI efforts to determine

safety and efficacy of promising cancer therapies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities.

2.5. On June 21, 1999, the Assistant Secretary of Defense (Health Affairs) expanded the successful partnership with the NCI by allowing TRICARE eligible family members to participate in NCI sponsored clinical trials in cancer prevention in addition to cancer treatment. Cancer prevention clinical trials include screening and early detection clinical trials. This expansion of the current demonstration will enhance continued NCI efforts to determine safety and efficacy of promising cancer prevention strategies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities.

2.6. While this demonstration provides an exception to current TRICARE benefit limitations, the Department hypothesizes that this increased access to innovative cancer strategies will occur at a cost comparable to that which the Department has experienced in paying for conventional care under the TRICARE Standard program. The results of the demonstration will provide a framework for determining the scope of DoD's continued participation in the NCI's clinical research efforts.

3.0. POLICY

NOTE: Effective June 21, 1999, the Department expanded the demonstration to include NCI sponsored cancer prevention, screening and early detection clinical trials.

3.1. Effective January 1, 1996, the cancer demonstration was authorized for those TRICARE-eligible patients selected to participate in NCI sponsored Phase II and Phase III studies for treatment of cancer. NCI sponsorship of clinical trials occurs through the Cancer Therapy Evaluation Program (CTEP), Cooperative Group Studies, NCI Grants or Cancer Center Studies. Evidence of NCI sponsorship in one of these categories will be that it is identified in the NCI comprehensive database, Physicians's Data Query (PDQ), or NCI supplements to that database; formal notification of approval from The Clinical Protocol Review and Monitoring Committee; or verification from the NCI project officer; or through protocols co-sponsored by the NCI and other Federal Agencies.

3.2. The DoD will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. DoD will cost-share all medical care required as a result of participation in NCI sponsored studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

3.2.1. The provider seeking treatment for a TRICARE-eligible family member in an NCI approved protocol has obtained preauthorization for the proposed treatment before initial evaluation; and

3.2.2. Such treatments are NCI sponsored Phase II or Phase III protocols; and

- 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

FIGURE 20-2-2 SAMPLE OF AUTHORIZATION LETTER FOR DOD CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION

Name of Inquirer

Title

Hospital Name (Phase of cancer prevention or treatment protocol:

Street Address type of cancer; title of protocol)

City, ST ZIP

Patient: **(Name of Patient) (Relationship to Sponsor, Sponsor Name, Rank, Branch of Service, Sponsor Status, Sponsor's SSN)**

Dear _____:

Our office has completed review of your **(Date of Letter)** application on behalf of **(Name of Patient)** for benefits under the Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration. Based on our finding the proposed protocol **(NCI Number of Approved Protocol)** is an NCI sponsored study, and meets the terms of the Demonstration, we are pleased to authorize this care for **(Name of Patient)**.

The Department of Defense intends to pay institutional and professional charges for cancer prevention and treatment for the patient named above if:

1. The provider seeking treatment for a TRICARE-eligible family member in an NCI approved cancer protocol has obtained preauthorization for the proposed clinical trial before initial evaluation; and
2. Such treatments are provided according to the NCI approved Phase II or Phase III cancer prevention or treatment protocol; and
3. The patient continues to meet entry criteria for said protocol; and
4. The institutional and individual providers are TRICARE-authorized providers.

Both institutional and professional charges will be reimbursed based on billed charges. The cancer center must submit all charges on the basis of fully itemized bills. Each service and supply must be individually identified. All cost-shares and deductibles applicable to TRICARE will also apply under this Demonstration as will co-pays for TRICARE Prime and USFHP enrollees. Questions regarding claims and reimbursement methodology will be provided by the contractor Demonstration case manager.

Because Demonstration benefits are not the same as TRICARE benefits, claims must be submitted to the appropriate contractor, referencing the Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration.

A copy of this letter must accompany any claim submitted for Demonstration reimbursement of care related to this patient's cancer prevention and treatment. Any treatment under protocols other than the one specifically approved in this letter must receive preauthorization.

TRICARE OPERATIONS MANUAL 6010.51-M, AUGUST 1, 2002

CHAPTER 20, SECTION 2

DEPARTMENT OF DEFENSE CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION

FIGURE 20-2-2 SAMPLE OF AUTHORIZATION LETTER FOR DoD CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION (CONTINUED)

Name of Facility

Re: Patient Name

Date

Thank you for allowing the Department of Defense to participate in the care of your patient.

Sincerely,

Title

cc:

-Beneficiary's Name and Mailing Address

FIGURE 20-2-3 SAMPLE OF DENIAL LETTER FOR DOD CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION

Name of Inquirer

Title

Hospital Name (Phase of cancer prevention or treatment protocol;

Street Address type of cancer; title of protocol)

City, ST ZIP

Patient: **(Name of Patient) (Relationship to Sponsor, Sponsor Name, Rank, Branch of Service, Sponsor Status, Sponsor's SSN)**

Dear _____:

Thank you for your **(Date of Letter or Facsimile)** application requesting care for **(Name of Patient)** under the terms of the Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration.

The Demonstration is authorized to fund cancer prevention and treatment when conducted under a Phase II or Phase III, NCI-sponsored study. Following review of the data you submitted for **(Name of Patient)**, we have determined that **(list one or more of the following two reasons for denial)**:

1. **(List Name of Protocol)** is not an NCI sponsored study.
2. **(List Name of Protocol)** is not Phase II or Phase III in design.

Therefore, it is our decision that this patient's proposed care does not qualify for reimbursement under the terms of the Demonstration. Since the Demonstration has no authority regarding the NCI sponsored studies, if a patient does not meet the criteria for enrollment, appeal rights do not apply.

I am sincerely sorry that we are unable to assist **(Name of Patient)** with these expenses.

Sincerely,

Title

cc:

-Patient's Name and Mailing address

FIGURE 20-2-4 SAMPLE OF NOTIFICATION LETTER TO BE ISSUED TO GEOGRAPHICAL CONTRACTOR OF PATIENT'S ENROLLMENT IN THE DOD CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION

FI/Contractor Name
Street Address
City, ST ZIP

Dear _____:

This letter is to notify you the following patient has enrolled in the Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration:

Name of Patient: _____

Sponsor's Social Security Number: _____

All claims associated with this patient's treatment while enrolled in the clinical trial shall be processed by this office, with the exception of individual prescription drug claims. If claims are received for services provided to this patient, please forward the claims to the following address: **(Appropriate Address)**.

If you have any questions or concerns, you may contact me at the address in the letterhead or call **(Appropriate Telephone Number)**.

Sincerely,

Title