Chapter 7 Section 24.1

Phase I, Phase II, And Phase III Cancer Clinical Trials

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1.0 DESCRIPTION

The Department of Defense (DoD) Cancer Prevention and Treatment Clinical Trials Demonstration was conducted from 1996 through March 2008 to improve access to promising new cancer therapies, assist in meeting the National Cancer Institute's (NCI's) 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. This Demonstration included Phase II and Phase III protocols sponsored by the NCI for the prevention, screening, early detection, and treatment of all types of cancer. The Demonstration ended on March 31, 2008 and applicable coverage guidance has been incorporated into this policy. A new Interagency Agreement between DoD and the NCI has been entered into which is effective April 1, 2008. Participation in Phase I studies may be approved on a case-by-case basis when the requirements listed below are met, effective February 14, 2011.

2.0 POLICY

2.1 Cancer clinical trial participation is authorized for those TRICARE-eligible patients selected to participate in NCI-sponsored Phase I, Phase II, and Phase III studies for the prevention, screening, early detection, and treatment of cancer. TRICARE 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. TRICARE 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:

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

2.1.2 Such treatments are NCI sponsored Phase I, Phase II, or Phase III protocols; and

2.1.3 The patient continues to meet entry criteria for said protocol; and

2.1.4 The institutional and individual providers are TRICARE-authorized providers.

2.2 In addition to the above requirements, all of the following conditions must be met for participation in Phase I cancer clinical trials:

2.2.1 Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative. Attending physician, Primary Care Manager (PCM), or oncologist referral to the trial, and the patient's subsequent acceptance to the trial fulfill this requirement; and

2.2.2 The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative. Attending physician, PCM, or oncologist referral to the trial, and the patient's subsequent acceptance to the trial fulfill this requirement; and

2.2.3 The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise. NCI sponsored trials meet this criteria; and

2.2.4 The enrollee's participation in such a trial would be appropriate based upon the satisfaction of the above criteria. Attending physician, PCM, or oncologist referral to the trial, and the patient's subsequent acceptance to the trial fulfill this requirement.

3.0 POLICY CONSIDERATIONS

3.1 Referral by Attending Physician

The attending physician, PCM, or oncologist shall determine the eligible patient's needs and consult with the TRICARE contractor's cancer clinical trials case manager/NCI to determine which, if any, Phase I, Phase II, or Phase III, NCI-sponsored studies are appropriate for the patient.

3.2 Identification of Eligible NCI-Sponsored Clinical Trials

3.2.1 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, Physician'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.

3.2.2 Unlike the NCI-sponsored protocols for CTEP, Cooperative Group Studies, or NCI Grants, 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.

3.2.3 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.

3.2.4 Requests for treatment in clinical trials overseas must be verified as to NCI sponsorship with the NCI project officer.

3.2.5 Protocols that are co-sponsored by the NCI and other Federal Agencies must be verified by the NCI project officer.

3.2.6 Some NCI-sponsored clinical trials are designated as multiple-phased trials (e.g., Phase I/II). Multi-phase NCI-sponsored clinical trials are eligible for TRICARE coverage as long as the beneficiary is a participant in a trial phase that would normally be covered in a single-phase trial.

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

3.4 Retroactive authorizations can be authorized in accordance with the provisions outlined in 32 CFR 199.4(g)(19).

3.5 Claims will be paid from the applicable underwritten Contract Line Item Number (CLIN) and submitted through normal TRICARE Encounter Data (TED) system processing as required in the TRICARE Systems Manual (TSM) with the applicable coding for cancer clinical trials with enrollment in Phase II and Phase III cancer clinical trials effective on or after April 1, 2008, and enrollment in Phase I cancer clinical trials effective on or after February 14, 2011.

3.6 Normal TRICARE eligibility, reimbursement, co-payments, cost-shares, deductibles, TRICARE for Life (TFL), and double coverage rules apply.

3.7 The contractor shall:

3.7.1 Provide a registered nurse to serve as case manager for inquiries and actions pertinent to the cancer clinical trials benefit.

3.7.2 Ensure the provider has submitted a letter on the facility's letterhead:

3.7.2.1 Provide the patient's name and the last four digits of the sponsor's Social Security Number (SSN); and

3.7.2.2 Certify the protocol is an NCI-sponsored study and providing the title and phase of the protocol and the NCI number of the protocol and/or other appropriate evidence of NCI sponsorship; and

3.7.2.3 Certify the patient meets all entry criteria for said protocol; and

3.7.2.4 Certify notification will be provided to the contractor's cancer clinical trials benefit case manager of the patient's registration date when treatment actually begins; and

3.7.2.5 Certify notification will be provided to the contractor's cancer clinical trials benefit case manager if the patient becomes ineligible for the study prior to the treatment.

3.7.3 Utilize the NCI's Comprehensive Cancer Database known as the PDQ, to assist in determining whether a particular study meets the requirements of the cancer clinical trials benefit 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 and phase of the study.

3.8 The contractor may at its discretion establish a dedicated toll-free telephone number to receive inquiries from both patients and providers regarding the cancer clinical trials benefit. If a dedicated toll-free telephone number is established, the phone shall be staffed seven hours a day during normal business hours in the contractor's time zone where the inquiries are received. In the absence of a dedicated toll-free number for cancer clinical trials benefit inquiries, contractors shall use their primary toll-free telephone inquiry system (see the TOM, Chapter 11, Section 6 and Chapter 20, Section 4).

The contractor may at its discretion establish a dedicated mailing address where cancer clinical trials benefit inquiries and claims shall be sent for expedited response and/or claims adjudication. In the absence of a dedicated mailing address for cancer clinical trials benefit inquiries and claims, contractors shall use their primary address(es) for written correspondence and claims (see the TOM, Chapter 11, Section 4 and 5, and Chapter 20, Section 4).

4.0 EXCLUSIONS

4.1 Care rendered in the National Institutes of Health (NIH) Clinical Center.

4.2 Costs associated with non-treatment research activities related to clinical trials.

5.0 EFFECTIVE DATES

5.1 April 1, 2008 for Phase II and Phase III cancer clinical trials.

5.2 February 14, 2011 for Phase I cancer clinical trials.

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