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TRICARE
MANAGEMENT ACTIVITY

MB&RS

CHANGE 71
6010.54-M
FEBRUARY 25, 2008

PUBLICATIONS SYSTEM CHANGE TRANSMITTAL FOR TRICARE POLICY MANUAL (TPM)

The TRICARE Management Activity has authorized the following addition(s)/ revision(s) to the 6010.54-M, issued 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 TOM, Change No. 59, and Aug 2002 TSM, Change No. 54.

Reta Michak
Chief, Office of Medical Benefits and Reimbursement Systems

ATTACHMENT(S): 28 PAGE(S)
DISTRIBUTION: 6010.54-M

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

REMOVE PAGE(S)	INSERT PAGE(S)
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Implementation date. The implementation date of a policy or instruction is not noted in the issuance as this date is determined by the terms of the contract modification between TMA and the contractor. Unless otherwise directed by TMA, contractors are not to identify finalized claims for readjudication under revised or new policy. However, the contractor shall readjudicate any denied claim affected by the policy that is brought to the contractor's attention by any source. Pending claims and denied claims in reconsideration shall be adjudicated using the current applicable policy.

To Be Determined (TBD) Dates. For those policies where a TBD date is referenced, the offeror can assume the change will be in effect prior to the first day of health care delivery of the new contract.

BENEFIT POLICY

Benefit policy applies to the scope of services and items which may be considered for cost-sharing by the TRICARE/CHAMPUS within the intent of the CFR Chapter 199.4 and Chapter 199.5.

The current edition of the American Medical Association's Physicians' Current Procedural Terminology (CPT) is incorporated by reference into this Manual to describe the scope of services potentially allowable as a benefit, subject to explicit requirements, limitations, and exclusions, in this Manual or in the 32 CFR 199.

Procedures listed in the CPT and the HCFA Common Procedure Coding System (HCPCS) may be cost-shared only when the contractor determines the procedure is "appropriate medical care" and is "medically or psychologically necessary" and is not "unproven" as defined in the 32 CFR 199.4(g)(15), and the procedure is not explicitly excluded in the TRICARE program. This general prohibition against the cost-sharing of unproven drugs, devices, and medical treatments or procedures is waived in connection with Phase II and Phase III cancer clinical trials sponsored or approved by the National Institutes of Health National Cancer Institute (NIH NCI) as defined in 32 CFR 199.4(e)(26).

PROGRAM POLICY

Program policy applies to beneficiary eligibility, provider eligibility, claims adjudication, and quality assurance. Program policy implementation instructions are found in the TRICARE Systems Manual and the TRICARE Operations Manual.

REIMBURSEMENT POLICY

Reimbursement policy sets forth the payment procedures used for reimbursing TRICARE claims. The related implementation instructions for these payment procedures are found in the TRICARE Systems Manual and TRICARE Operations Manual.

The TRICARE Reimbursement Manual provides the methodology for pricing allowable services and items and for payment to specific categories and types of authorized providers. These methods allow the contractor to price and render payment for specific examples of services or items which are not explicitly addressed in the Manual but which belong to a

general category or type which is addressed in the Manual.

- END -

CHAPTER 1

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31. Transfer factor (TF). This is a dialyzable leukocyte extract (DLE) used to transfer delayed hypersensitivity from an immune to a nonimmune subject and is considered unproven.

See Chapter 1, Section 3.1 for policy on Rare Diseases.

See Chapter 7, Section 24.1 for policy on cancer clinical trials.

See Chapter 8, Section 5.1 for policy on Medical Devices, including coverage of Humanitarian Use Devices and a FDA-approved Investigational Device Exemption (IDE) categorized by the FDA as non-experimental/investigational (FDA Category B).

See Chapter 8, Section 9.1 for policy on off-label use of drugs.

- END -

2. For patients under 18 years of age with a relapsed leukemia, when histocompatible related or unrelated donors are not available, parental CD34++ stem cell transplantation with 2-3 antigen mismatch is allowed.

I. Benefits will not be allowed for stem cell harvesting and/or cryopreservation and umbilical cord blood stem cell harvesting and/or cryopreservation until the stem cell reinfusion has been completed. In the event that the patient expires prior to the stem cell reinfusion being completed, benefits for the harvesting may be allowed.

J. Benefits are allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

K. Benefits may be allowed for Deoxyribonucleic Acid - Human Leucocyte Antigen (DNA-HLA) tissue typing in determining histocompatibility.

L. Charges for stem cell and umbilical cord blood preparation and storage shall be billed through the transplantation facility in the name of the TRICARE patient.

M. Charges for the umbilical cord blood bank may be allowed only for patients who have undergone a covered transplant.

N. Claims for services and supplies related to the HDC and transplant for beneficiaries under the age of 18 will be reimbursed based on billed charges. Claims for HDC and transplant for adult patients, 18 years and older, will be reimbursed under the Diagnostic Related Group (DRG) payment system. Outpatient institutional facility charges will be paid as billed. Professional services are reimbursed under the CHAMPUS Maximum Allowable Charge (CMAC) Methodology.

O. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Benefits for advanced life support air ambulance (to include attendant) may be preauthorized by the appropriate preauthorizing authority on an individual case basis in conjunction with the preauthorization for the services themselves.

P. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for determining if the patient meets the coverage criteria. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization for HDC with ABMT or PSCT will be reimbursed only under Point of Service rules.

IV. EXCLUSIONS

Benefits will not be paid for:

A. HDC with ABMT or Autologous PSCT, Allogeneic BMT or Allogeneic PSCT, with or without HDC, or Allogeneic Umbilical Cord Blood transplantation, with or without HDC, if the patient has a concurrent condition (other existing illness) that would jeopardize the achievement of successful transplantation.

B. Expenses waived by the transplant center (i.e., beneficiary/sponsor not financially liable).

C. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant, or research program; unproven procedure).

D. Administration of an unproven immunosuppressant drug that is not FDA approved.

E. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members).

F. Transportation of a donor.

G. Allogeneic bone marrow transplantation for treatment of low grade non-Hodgkin's lymphoma is not a benefit.

H. Autologous umbilical cord blood transplantation therapy as this procedure is considered unproven.

I. Allogeneic bone marrow transplantation for neuroblastoma as this procedure is considered unproven.

J. Allogeneic donor bone marrow transplantation (infusion) performed with or after organ transplants for the purpose of increasing tolerance of the organ transplant is considered unproven.

K. HDC with ABMT or PSCT is not a benefit for treatment of desmoplastic small round-cell tumor.

L. HDC with ABMT or PSCT is not covered for treatment of breast cancer.

M. HDC with allogeneic BMT is not a benefit for treatment of Waldenstrom's macroglobulinemia.

N. HDC with stem cell rescue is not a benefit for the treatment of epithelial ovarian cancer.

O. HDC with allogeneic stem cell transplantation is not covered for the treatment of cold agglutinin disease.

P. Donor lymphocyte infusion if not specifically listed as covered in paragraph III.D. under POLICY above.

V. EFFECTIVE DATES

A. May 1, 1987, for HDC with ABMT or PSCT for Hodgkin's disease, non-Hodgkin's lymphoma and neuroblastoma.

B. November 1, 1987, for HDC with ABMT or PSCT for acute lymphocytic and nonlymphocytic leukemias.

C. November 1, 1983, for HDC with allogeneic bone marrow transplants using related donors.

D. July 1, 1989, for HDC with allogeneic bone marrow transplants using unrelated donors.

E. July 11, 1996, for HDC with ABMT or PSCT for multiple myeloma.

F. January 1, 1994, for HDC with ABMT and PSCT for Wilms' tumor.

G. January 1, 1995, for allogeneic umbilical cord blood transplants.

H. January 1, 1994, for HDC with ABMT or PSCT for chronic myelogenous leukemia.

I. January 1, 1996, for HDC with ABMT or PSCT for Waldenstrom's macroglobulinemia.

J. January 1, 1996, for allogeneic bone marrow transplants using related 3 antigen mismatch donors for patients with undifferentiated leukemia, Chronic Myelogenous Leukemia (CML), aplastic anemia, Acute Lymphocytic Leukemia (ALL) or Acute Myelogenous Leukemia (AML).

K. October 1, 1996, for HDC with ABMT or PSCT for AL Amyloidosis.

L. January 1, 1995, for allogeneic bone marrow transplant for hypereosinophilic syndrome.

M. May 1, 1997, for HDC with ABMT or PSCT for trilateral retinoblastoma/ pineoblastoma.

N. January 1, 1997, for HDC with ABMT or PSCT for follicular lymphoma.

O. January 1, 1997, for HDC with ABMT or PSCT for non-Hodgkin's lymphoma in first complete remission.

P. November 28, 1997, for HDC with ABMT or PSCT for Hodgkin's disease in second or third remission.

Q. January 1, 1996, for HDC with allogeneic BMT for multiple myeloma.

R. July 1, 1999, for HDC with ABMT or PSCT for germ cell tumors in a second or subsequent relapse.

S. January 1, 1998, for HDC with ABMT or PSCT for osteosarcoma (osteogenic sarcoma).

T. June 1, 1995, for allogeneic BMT for Chediak-Higashi syndrome.

U. January 1, 1998, for allogeneic peripheral stem cell transplantation.

V. June 1, 2003, for Langerhans Cell Histiocytosis, refractory to conventional treatment.

W. January 24, 2002, for allogeneic stem cell transplant for Hodgkin's disease.

X. May 19, 2005, for tandem autologous peripheral stem cell transplant for high-risk neuroblastoma.

- END -

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	FIGURE 7-22.1-1 -Telehealth Originating Site Facility Fee
23.1	Augmentative Communication Devices (ACD)
24.1	Phase II And Phase III Cancer Clinical Trials

CHAPTER 7
SECTION 24.1

PHASE II AND PHASE III CANCER CLINICAL TRIALS

ISSUE DATE:
AUTHORITY: 32 CFR 199.4(e)(26)

I. 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) 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 (see the TRICARE Operations Manual (TOM), Chapter 20, Section 2). The Demonstration is to end 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.

II. POLICY

A. Cancer clinical trial participation is authorized for those TRICARE-eligible patients selected to participate in NCI-sponsored 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:

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

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

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

III. POLICY CONSIDERATIONS

A. Referral by Attending Physician.

The attending physician, Primary Care Manager (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 II or Phase III, NCI-sponsored studies are appropriate for the patient.

B. Identification of eligible NCI-sponsored clinical trials.

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, 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.

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. 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.

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

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

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.

C. 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.

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

E. 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 effective on or after April 1, 2008.

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

G. The contractor shall:

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

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

a. Providing the patient's name and the last four digits of the sponsor's Social Security Number (SSN); and

b. Certifying 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

c. Certifying the patient meets all entry criteria for said protocol; and

d. Certifying 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

e. Certifying 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. Utilize 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 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.

H. 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 12, Section 7 and Chapter 22, 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 12, Section 5, Chapter 12, Section 6, and Chapter 22, Section 4).

I. The Cancer Clinical Trials Demonstration project rules in the TOM Chapter 20, Section 2, will continue to apply to those TRICARE beneficiaries who began participation in Cancer Clinical Trials Demonstration before termination of the Demonstration. Such rules will continue to apply until the beneficiary is discharged from the clinical trial.

IV. EXCLUSIONS

A. Care rendered in the National Institutes of Health Clinical Center.

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

C. Phase I clinical trials (including Phase I arm of multi-phase clinical trials).

V. EFFECTIVE DATE April 1, 2008.

- END -

CHAPTER 9
SECTION 1.1

GENERAL

ISSUE DATE: July 3, 1997
AUTHORITY: 32 CFR 199.5

I. DESCRIPTION

A. The Extended Care Health Option (ECHO) is a supplemental program to the TRICARE Basic Program and provides eligible active duty family members with an additional financial resource for an integrated set of services and supplies designed to assist in the reduction of the disabling effects of the beneficiary's qualifying condition (see Chapter 9, Sections 2.1 through 2.4). The ECHO is not an enrollment program but does require registration (see Chapter 9, Section 3.1).

B. The ECHO replaces the Program for Persons with Disabilities (PFPWD). The PFPWD as published prior to TRICARE Policy Manual Change 12, (dated December 7, 2004), remains in full force and effect until this change is implemented. Claims for services or items authorized and provided under the PFPWD will be processed in accordance with the policies of the PFPWD.

II. POLICY

A. The ECHO is available only to eligible active duty family members.

B. Eligibility and registration are prerequisites to ECHO benefits being authorized.

C. Written authorization for ECHO benefits is a prerequisite to claim adjudication.

D. ECHO-eligible beneficiaries who are enrolled in TRICARE Prime shall meet all applicable requirements of that program, including those regarding the assignment and use of a Primary Care Manager when services are requested and provided through the ECHO.

E. TRICARE is primary payer for medical services and items that are provided under Part C of the Individuals with Disabilities Education Act in accordance with the Individualized Family Service Plan and which are otherwise allowable under the TRICARE Basic Program or the ECHO.

III. EXCLUSIONS

A. All benefits available through the TRICARE Basic Program are excluded from the ECHO.

B. Inpatient care for medical or surgical treatment of an acute illness, or of an acute exacerbation of the qualifying condition. These services may be cost-shared through the Basic Program.

C. Structural alterations to living space and permanent fixtures, including alterations necessary to accommodate installation of equipment or to facilitate entrance or exit.

D. Except as provided by the ECHO Home Health Care (EHHC) benefit (Chapter 9, Section 15.1) homemaker services that provide assistance with household chores are excluded.

E. Dental care and orthodontic treatment.

F. The price differential between the price for a type of accommodation which provides services or features that exceed the requirements of the beneficiary's condition for safe transport and the price for a type of accommodation without those deluxe features. Payment of such price differential is the responsibility of the beneficiary.

G. Durable equipment is excluded from the ECHO when:

1. The beneficiary is a patient in an institution or facility that ordinarily provides the same type of equipment to its patients at no additional charge in the usual course of providing services; or

2. The item is available to the beneficiary from a Uniformed Services Medical Treatment Facility (USMTF); or

3. The item has deluxe, luxury, immaterial or nonessential features that increase the cost to the government relative to a similar item without those features; or

4. The item is duplicate equipment as defined in 32 CFR 199.2.

H. Maintenance agreements for beneficiary-owned equipment are excluded.

I. Services or items for which the beneficiary or sponsor has no legal obligation to pay, or for which no charge would be made if the beneficiary was not eligible for benefits.

J. Services or items paid for, or eligible for payment, directly or indirectly by a Public Facility, as defined in 32 CFR 199.2, or by the Federal government, other than the Department of Defense (DoD), are excluded, except when such services or items are eligible for payment under a State plan for medical assistance under Title XIX of the Social Security Act (Medicaid).

K. Services and items provided as a part of a scientific clinical study, grant, or research program.

L. Unproven services and items whose safety and efficacy have not been established as described in 32 CFR 199.4, except for Phase II and Phase III cancer clinical trials sponsored or

approved by the National Institutes of Health National Cancer Institute (NIH NCI) as described in 32 CFR 199.4(e)(26).

M. Services or items provided or prescribed by a member of the beneficiary's immediate family, or a person living in the beneficiary's or sponsor's household.

N. Services or items ordered by a court or other government agency that are not otherwise an allowable ECHO benefit.

O. Additional or special charges for excursions, except for other otherwise allowable transportation, even when they are part of a program offered by an approved provider.

P. Drugs and medicines which do not meet the requirements of 32 CFR 199.4.

Q. Therapeutic absences from an inpatient facility.

R. Custodial care, as defined in 32 CFR 199.2, as a stand alone ECHO benefit is excluded. Services provided in support of activities of daily living may be cost-shared only when provided through the EHHC benefit (see Chapter 9, Section 15.1).

S. Domiciliary care, as defined in 32 CFR 199.2, may not be cost-shared through the ECHO.

T. Services for a beneficiary aged 3 to 21 that are written in the beneficiary's special education Individualized Educational Program (IEP) and that are required to be provided without charge by the local public education facility in accordance with the Individuals with Disabilities Education Act (IDEA).

IV. EFFECTIVE DATE

A. September 1, 2005.

B. The cancer clinical trials exception in paragraph III.L., is effective as provided in Chapter 7, Section 24.1 and the TRICARE Operations Manual (TOM), Chapter 20, Section 2.

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