CHAPTER 8
SECTION 9.1

PHARMACY BENEFITS PROGRAM

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I. DESCRIPTION

A. General

The TRICARE Pharmacy Benefit includes retail and mail order prescription services, medications provided by physicians and other appropriate clinicians, and medications provided in support of home health care. TRICARE uses a number of contractors to administer the benefit.

B. Retail Prescription Service

Retail pharmacy services, network and non-network, will be provided under a TRICARE Retail Pharmacy Contract, and will be subject to the Uniform Formulary, when it becomes effective. The retail pharmacy contractor is responsible for administering claims related to pharmaceuticals prescribed by and dispensed by a physician or other authorized provider with a National Council of Prescription Drug Programs (NCPDP) designation.

C. Mail Order Prescription Service

Mail order prescription services will be provided under a TRICARE Mail-Order Pharmacy Contract. The mail order program formulary is currently a Preferred Agent Concept. The Preferred Agent List can be found at http://www.pec.ha.osd.mil/nmop/nmophome.htm. Formulary management of the mail order benefit will be subject to the Uniform Formulary upon the effective date of the Pharmacy Benefits Program final rule.

D. Other Pharmaceutical Delivery Venues

Adjudication of claims relating to pharmaceuticals dispensed in pharmacy delivery venues other than retail pharmacies or the TRICARE Mail Order Pharmacy (for example, physician's office, home health care agency, specialty pharmacy) are the responsibility of the Managed Care Support Contractor(s).

II. POLICY

A. Formulary

Formulary management will be the responsibility of the Government as defined by 32 CFR 199.21, Pharmacy Benefits Program. This regulation establishes procedures for the inclusion of pharmaceutical agents on a Uniform Formulary based upon relative clinical effectiveness and cost effectiveness; establishes cost-sharing requirements, including a tiered co-payment structure, for generic, formulary and non-formulary pharmaceutical agents; establishes procedures to assure the availability of pharmaceutical agents not included on the Uniform Formulary to eligible beneficiaries at the non-formulary cost-share tier; establishes procedures to provide, when clinically necessary, pharmaceutical agents not included on the Uniform Formulary under the same terms and conditions as an agent on the Uniform Formulary; establishes procedures to assure the availability of clinically appropriate non-formulary pharmaceutical agents to members of the uniformed services; establishes procedures for prior authorization when required; and establishes a Department of Defense Pharmacy and Therapeutics Committee (DoD P&T Committee) and a Uniform Formulary Beneficiary Advisory Panel. All formulary decisions, to include prior authorization requirements, designation of non-formulary agents, quantity limits, and other medication use policies will be communicated to all contractors who have responsibility for administering the TRICARE Pharmacy benefit and to the Managed Care Support Contractors.

The prescription drug benefit under TRICARE provides cost-sharing for drugs and medicines that (1) are approved for marketing by the U.S. Food and Drug Administration (FDA), and (2) by United States law require a physician's or other authorized individual professional provider prescription (acting within the scope of their license), and (3) are actually ordered or prescribed by an authorized provider in accordance with state and federal law. The benefit does not include prescription drugs for medical conditions that are expressly excluded from the TRICARE benefit by statute or regulation. The Pharmacy Benefits Program will include a Uniform Formulary of pharmaceutical agents that will assure the availability of pharmaceutical agents in the complete range of therapeutic classes authorized under the TRICARE prescription drug benefit.

B. Utilization Management

Utilization management is the responsibility of the contractor with contractual responsibility for the venue distributing the pharmaceuticals. Should another contractor require data about pharmaceutical prescribing practices of clinicians or the pharmaceuticals prescribed to a patient, the contractor requiring the information may submit a request for data to the contracting officer. The requesting contractor shall commit to paying all costs associated with retrieving and providing any data. No contractor will be required to develop or provide data that is not available in the contractor's data warehouse.

C. General Prescription Coverage

1. Labeled Indications. Drugs may be cost-shared when:

a. The drug is approved for marketing by the U.S. Food and Drug Administration;

b. The drug is prescribed by a provider, acting within the scope of his/her license, for its labeled indication; and

c. The drug is furnished by a provider in accordance with all applicable state laws and licensing requirements.

2. Off-label use. Drugs may be cost-shared for off-label uses when determined, by the contractor with responsibility for the venue distributing the drugs, that reliable evidence demonstrates such usage is safe and effective. As presented in order of relative weight in 32 CFR 199.2, reliable evidence means:

a. Well controlled studies of clinical meaningful endpoints, published in refereed medical literature.

b. Published formal technology assessments.

c. Published reports of national professional medical associations.

d. Published national medical policy organizations.

e. Published reports of national expert opinion organizations.

3. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be cost-shared as if FDA approved.

4. Insulin and related supplies may be cost-shared for diabetic patients, regardless of whether or not a prescription is required under state law.

5. Orphan Drugs. Pharmaceutical agents with FDA "orphan drug" designation and marketing approval may be cost-shared when used in the treatment of a rare disease or condition. For the purpose of the pharmacy benefits program, TRICARE adopts the FDA definition of the term "rare disease or condition".

6. Legend vitamins may be cost-shared only when used as a specific treatment of a medical condition. In addition, prenatal vitamins that require a prescription in the United States may be cost-shared. Prenatal vitamins requiring a prescription are covered for prenatal care only.

7. Some drugs require prior authorization. For these drugs, prior authorization request forms and criteria, in addition to other formulary information, are available at: http://www.pec.ha.osd.mil or http://www.pec.ha.osd.mil/PA_Criteria_and_forms.htm.

D. Eligibility

1. Uniformed Service members who are on active duty;

2. All beneficiaries authorized TRICARE benefits per 32 CFR 199.3;

3. Medicare eligible beneficiaries:

a. Pursuant to Section 711 of the FY 2001 National Defense Authorization Act, Medicare Eligible beneficiaries based on age, whose TRICARE eligibility is determined by 10 U.S.C. Section 1086, are eligible for Medicare Part A and, except as provided in paragraph III.B. below, are enrolled in Medicare Part B, are eligible for the TRICARE pharmacy benefits program, effective April 1, 2001.

b. Individuals, who before April 1, 2001, have attained the age of 65 and who are not enrolled in Medicare Part B are eligible for the TRICARE Senior Pharmacy Program; and

4. Overseas TRICARE beneficiaries listed in DEERS (with APO or FPO address) are eligible for the TRICARE Mail Order Program. For these beneficiaries a prescription is required for a U.S. Food and Drug Administration approved prescription drug from an authorized provider who is licensed to practice in the United States.

E. Reimbursement

1. The prescription drug claims for eligible beneficiaries will be reimbursed in accordance with the applicable reimbursement sections of the TRICARE Reimbursement Manual. Beneficiaries shall pay a co-pay in accordance with Chapter 12, Section 11.1 or TRICARE Reimbursement Manual, Chapter 2, Addendum A as appropriate. All deductibles and co-pays apply towards the catastrophic cap.

2. Beneficiary appeal rights are governed by 32 CFR 199.10.

III. EXCLUSIONS

A. Drugs prescribed or furnished by a member of the patient's immediate family.

B. Drugs, including compounded preparations, that are available over the counter.

C. Group C Designation. Investigational drugs with FDA "Group C" designation have reproducible efficacy in one or more specific tumor types. Such a drug has altered or is likely to alter the pattern of treatment of the disease and can be safely administered by properly trained physicians without specialized supportive care facilities. TRICARE may not cost-share use of Group C designated drugs because authorization for Group C distribution for a specific indication is not equivalent to formal FDA approval for that indication. Medical care related to the use of Group C designated drugs may be cost-shared only when the care would have been provided in the absence of the use of the Group C designated drug.

D. Orphan drugs without marketing approval, but which are made available on a compassionate use basis, may not be cost-shared.

E. Treatment Investigational New Drugs (IND). Under the FDA treatment IND (investigational new drug) regulations enacted in 1987, drugs that are in controlled clinical trials can be provided outside those trials to treat patients with serious or immediately life-

threatening diseases for which no comparable or satisfactory alternate therapy exists. TRICARE may not cost-share treatment INDs because they have not received FDA marketing approval. However, medical care related to the use of treatment INDs may be cost-shared when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

F. Irinotecan (Camptosar®) for treatment of metastatic esophageal cancer is unproven.

IV. EFFECTIVE DATES

A. Labeled uses: the date of FDA approval for the specific indication.

B. Off-labeled uses: the date that reliable evidence establishes the safety and efficacy of the drug for that specific use.

C. Orphan drugs: the date of FDA marketing approval.

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