Chapter 8 Section 9.1

Pharmacy Benefits Program

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Authority: 32 CFR 199.2(b), 32 CFR 199.4(b)(2)(vi), (b)(3)(iii), (b)(5)(v), (d)(3)(vi), (e)(11)(i), 32 CFR 199.5(d)(12); 32 CFR 199.17, and 10 USC 1074g

1.0 DESCRIPTION

1.1 General

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

1.2 Retail Prescription Service

Retail pharmacy services, network and non-network, will be provided under a TPharm contract and will be subject to the Uniform Formulary. The TRICARE formulary is found at http://www.tricareformularysearch.org. The retail pharmacy contractor is responsible for administering claims related to pharmaceuticals dispensed by an authorized provider with a National Council of Prescription Drug Programs (NCPDP) or other nationally recognized pharmacy designation.

1.3 Mail Order Prescription Service

Mail order prescription services are provided under a TPharm contract and will be subject to the Uniform Formulary. The TRICARE formulary is found at http://www.tricareformularysearch.org.

1.4 Medical Claims That Include Pharmaceutical Agents

Pharmaceutical agents provided by physicians and other appropriate clinicians, and pharmaceutical agents provided in support of home health care are processed by the Managed Care Support Contractor(s) (MCSC). Claims for pharmaceutical agents (e.g., injectables) not appropriate for self-administration are the responsibility of the MCSC.

1.5 Overseas Claims

The TRICARE overseas claims processor (see the TRICARE Operations Manual (TOM), Chapter 24, Section 9) processes pharmaceutical claims from most overseas locations. As of June 1, 2004, the TPharm contractor processes network and non-network retail pharmaceutical claims in Puerto Rico, the U.S. Virgin Islands, Northern Mariana Islands, and Guam.

2.0 POLICY

2.1 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 copayment 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 pharmacy benefit.

2.2 General Prescription Coverage

2.2.1 The Pharmacy Benefits Program generally requires mandatory substitution of generic drugs in accordance with 32 CFR 199.21(j)(2). If state law prohibits generic substitution on drugs, the contractor, at the direction of the government, shall be able to process the brand product.

2.2.2 Eligible beneficiaries shall pay a copayment for drug claims that are cost-shared under the Pharmacy Benefit Program in accordance with the TRICARE Reimbursement Manual (TRM), Chapter 2, Addendum B.

2.2.3 TRICARE is the secondary payor on claims where other health insurance (OHI) coverage exists. OHI claims are reimbursed in accordance with TRM, Chapter 4, Section 3. Reimbursement will be the lesser of the TRICARE allowed amount or the remaining amount after OHI payment.

2.2.4 Labeled Indications. Pharmaceutical agents may be cost-shared when:

- The pharmaceutical agent is approved for marketing by the U.S. Food and Drug Administration (FDA);
- The pharmaceutical agent is prescribed by a provider, acting within the scope of his/her license, for its labeled indication; and
- The pharmaceutical agent is furnished by a provider in accordance with all applicable state laws and licensing requirements.

2.2.5 Coverage may also be considered for unlabeled or off-label uses of drugs that are FDA approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of unlabeled or off-label uses requires review for medical necessity,

and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. As presented in order of relative weight in 32 CFR 199.2, reliable evidence means:

- Well controlled studies of clinical meaningful endpoints, published in refereed medical literature.
- Published formal technology assessments.
- Published reports of national professional medical associations.
- Published national medical policy organizations.
- Published reports of national expert opinion organizations.

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

2.2.7 Insulin and related supplies may be cost-shared for known diabetic patients, even though a prescription may not be required for purchase.

2.2.8 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."

2.2.9 Legend vitamins may be cost-shared only when used as a specific treatment of a medical condition.

2.2.10 The DoD establishes quantity limits and prior authorizations for certain pharmaceutical agents. Prior authorization request forms, criteria, and list of pharmaceutical agents with established quantity limits are available at: http://www.tricare.mil/pharmacy/unif_form.cfm.

3.0 EXCLUSIONS

3.1 Pharmaceutical agents prescribed or furnished by a member of the patient's immediate family or a person living in the beneficiary's or sponsor's household.

3.2 Pharmaceutical agents, including compounded preparations, that are available over the counter.

3.3 Investigational pharmaceutical agents 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 pharmaceutical agents, 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 pharmaceutical agents may be cost-shared only when the care would have been provided in the absence of the use of the Group C-designated drug.

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

3.5 Under the FDA treatment Investigational New Drug (IND) regulations enacted in 1987, pharmaceutical agents 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.

3.6 Medical foods are not covered under the TPharm benefit. The term "medical food", as defined in section 5(b) of the Orphan Drug Act (21 USC § 360ee(b)(3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

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

4.0 UTILIZATION MANAGEMENT

4.1 Utilization management is the responsibility of the contractor with 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 (CO). 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 are not available in the contractor's data warehouse.

4.2 The contractors shall screen prescription claims for potential over-utilization and substance abuse. If a potential drug abuse situation is identified by the MCSC, the pharmacy contractor, a private physician, a physician-reviewer in the course of business for the contractor, or a physician in a hospital setting, the beneficiary shall be placed on 100% prepayment review. The Government cannot cost share benefits to support or maintain potential drug abuse situations. This is true, whether or not the pharmaceutical agents are obtained by legal means, and are otherwise eligible for benefit consideration under other circumstances. The pharmacy contractor, in conjunction with the managed care support contractor or responsible military treatment facility shall:

4.2.1 Pend all claims for the beneficiary;

4.2.2 Establish the necessity for the pharmaceutical agents and their appropriateness based on diagnosis or definitive symptoms;

4.2.3 Deny all related claims if a drug abuse situation does exist, including office visits or emergency room visits if the purpose of the visit was to obtain pharmaceutical agents; and

4.2.4 Reopen prior claims (most recent 12 months) for the beneficiary and review those claims to determine whether or not drug abuse existed at the time the earlier claims were paid. If drug abuse is ascertained for prior claims, recoupment action shall be taken for the erroneous payments.

4.3 The contractor shall request the beneficiary to select a physician, who will act as the primary care physician coordinating all care and making referrals when appropriate. For Prime enrollees, the contractors shall take action to manage the beneficiary's treatment as appropriate. The contractor shall not submit these cases to the TMA Program Integrity (PI) Office unless potential fraud, such as altered prescriptions or drug receipts, or aberrant prescribing patterns by the physician is identified.

4.4 Additionally, beneficiaries will be required to designate a primary care provider responsible for managing all prescriptions. Beneficiaries will be informed that any prescription written by other than the designated provider shall be denied authorization for dispensing through network retail pharmacies and, additionally, that any TRICARE claim for prescriptions filled by a non-network retail pharmacy will be denied reimbursement. This process will be coordinated between the managed care support contractor, the pharmacy contractor, and the Pharmacy Operations Center (POC).

Note: Beneficiaries are entitled to benefits by law. Beneficiaries cannot be sanctioned to preclude them from seeking benefits for medical care which is appropriate and medically necessary.

5.0 EFFECTIVE DATES

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

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

5.3 Orphan pharmaceutical agents: the date of FDA marketing approval.

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