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.tricare.mil/pharmacyformulary. 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.tricare.mil/pharmacyformulary.

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 Infusion Drug Therapy Delivered In The Home

When injectable and infusion drug therapy are medically necessary, and delivery and administration in the home is appropriate the MCSC shall provide prior authorization of injectable or infused drugs to a TRICARE authorized pharmacy in order for the pharmaceutical agent to be

fulfilled under the pharmacy benefit pursuant to Section 20.1, "Infusion Drug Therapy Delivered in the Home".

1.6 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 off-label uses of drugs and biologics.

2.2.5.1 Off-label drugs and biologics must meet the definition of Off-Label Use of a Drug or Device as described in32 CFR 199.2:

> Off-Label Use of a Drug or Device. A use other than an intended use for which the prescription drug, biologic or device is legally marketed under the Federal Food, Drug, and Cosmetic Act or the Public Health Services Act. This includes any use that is not included in the approved labeling for an approved drug, licensed biologic, approved device or combination product; any use that is not included in the cleared statement of intended use for a device that has been determined by the Food and Drug Administration (FDA) to be substantially equivalent to a legally marketed predicate device and cleared for marketing; and any use of a device for which a manufacturer or distributor would be required to seek pre-market review by the FDA in order to legally include that use in the device's labeling.

2.2.5.2 Approval for reimbursement of off-label uses of drugs and biologics reimbursed by the medical program shall be provided by the MCSC. The MCSC may provide approval for the reimbursement of off-label uses when the off-label use is medically necessary and demonstrations from medical literature, national organizations, or technology assessment bodies show that the off-label use of the drug or biologic is safe, effective and in accordance with nationally accepted standards of practice in the medical community. If the drug is FDA approved and the off-label use is medically necessary, supported by medical literature identified by the MCSC, which indicates the drug is nationally accepted as standard practice, and is not otherwise excluded, the MCSC may approve the cost-sharing for the off-label drug. Drugs provided by the TRICARE Overseas Program (TOP) shall continue to follow the policies established in Chapter 12, TRICARE Operations Manual (TOM), Chapter 24, and the TOP contract.

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. 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.

2.2.10 Pharmaceutical agents intended to promote smoking cessation, including legend and Over-The-Counter (OTC) drugs, may be cost-shared when approved by the Director, Defense Health Agency (DHA) for inclusion in the DoD Smoking Cessation Program, outlined in Public Law 110-417, section 713, when dispensed at the TRICARE Mail Order Pharmacy (TMOP) to beneficiaries deemed eligible under the aforementioned law.

2.2.11 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/CoveredServices/Pharmacy/Drugs/PriorAuth.aspx.

2.2.12 National Defense Authorization Act (NDAA) Fiscal Year (FY) 2015, Section 702 mandates beneficiaries to obtain select brand name maintenance medications from the TMOP or the Military Treatment Facility (MTF) pharmacy beginning October 1, 2015. Active Duty Service Members (ADSMs) are exempt. TOP TRICARE For Life (TFL) beneficiaries, with the exception of those beneficiaries residing in the U.S. territories, may not be eligible for this program. In order to be eligible they need to be residing in a country that allows use of TMOP, have prescriptions written by a U.S. licensed providers, and have an APO/FPO mailing address.

2.2.12.1 Maintenance medications are defined as medications prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. Those maintenance medications which are clinically appropriate and cost-effective to dispense at TMOP will be included in the program as select maintenance medications. Exceptions may be granted per the following guidelines.

2.2.12.2 A refill is defined as either a subsequent filling of an original prescription under the same prescription number (or other authorization as the original prescription), or a new original prescription for the same medication, strength and form issued at or near the end date of an earlier prescription.

2.2.12.3 DHA will establish, maintain, and periodically revise and update a list of select maintenance medications accessible at http://www.health.mil/SelectDrugList and by telephone through the pharmacy contractor's call center.

2.2.12.4 The NDAA authorizes a waiver of the mail order requirement based on patient needs and other appropriate circumstances. This waiver is obtained through an administrative override request to the TRICARE pharmacy contractor under procedures established by the Director, DHA. There is a blanket waiver for prescription medications that are for acute care needs. There is also a blanket waiver for prescriptions covered by OHI. There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstances (i.e., nursing home residents).

2.2.12.5 The pharmacy contractor shall notify beneficiaries of the new rules and the mechanisms which will allow them to receive adequate medication during their transition to TMOP.

2.2.12.6 The pharmacy contractor shall provide a toll free number to assist beneficiaries in transferring their prescriptions from retail pharmacies to TMOP.

2.2.12.7 Beneficiaries shall be advised that they may receive up to two, 30-day fills at a retail pharmacy while they transition their prescription. The beneficiary shall be contacted after each of

these two fills and advised that the prescription must be transferred. Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy contractor for assistance.

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 MCSC or responsible MTF 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 DHA 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 MCSC, 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 PRICING STANDARDS FOR RETAIL PHARMACY PROGRAM

As required by 10 USC 1074g(f), with respect to any prescription filled after January 28, 2008, the TRICARE Retail Pharmacy program shall be treated as an element of the DoD for purposes of the procurement of drugs by Federal agencies under 38 USC 8126 to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in such section 8126. A written agreement by a manufacturer to honor the pricing standards required by 10 USC 1074g(f) is a requirement for all pharmaceuticals provided through retail network pharmacies. If a manufacturer has not executed such an agreement then the prescription will not be filled by the network retail

pharmacy unless the patient/pharmacy has obtained a preauthorization for the drug.

6.0 EFFECTIVE DATES

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

6.2 Off-labeled uses: the date that medical literature as described in paragraph 2.2.5 establishes the safety and efficacy of the drug for that specific use.

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

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