



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE  
HEALTH AFFAIRS

16401 EAST CENTRETECH PARKWAY  
AURORA, COLORADO 80011-9066

TRICARE  
MANAGEMENT ACTIVITY

**MB&RB**

**CHANGE 92  
6010.57-M  
JULY 11, 2013**

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL  
FOR  
TRICARE POLICY MANUAL (TPM), FEBRUARY 2008**

The TRICARE Management Activity has authorized the following addition(s)/revision(s).

**CHANGE TITLE: NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FISCAL YEAR (FY) 2009,  
SECTION 713, SMOKING CESSATION PHARMACEUTICALS**

**CONREQ:** 16444

**PAGE CHANGE(S):** See page 2.

**SUMMARY OF CHANGE(S):** This change adds language that allows approved pharmaceuticals for smoking cessation available at the TRICARE Mail Order Pharmacy (TMOP).

**EFFECTIVE DATE:** March 29, 2013.

**IMPLEMENTATION DATE:** Upon direction of the Contracting Officer.

**This change is made in conjunction with Feb 2008 TRM, Change No. 82.**

**CORN.GLENN  
.J.1157445967**

Digitally signed by  
CORN.GLENN.J.1157445967  
DN: c=US, o=U.S. Government, ou=DoD,  
ou=PKI, ou=TMA,  
cn=CORN.GLENN.J.1157445967  
Date: 2013.07.09 07:48:07 -06'00'

**Ann N. Fazzini  
Chief, Medical Benefits and  
Reimbursement Branch**

**ATTACHMENT(S): 6 PAGE(S)  
DISTRIBUTION: 6010.57-M**

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

**CHANGE 92**  
**6010.57-M**  
**JULY 11, 2013**

**REMOVE PAGE(S)**

**CHAPTER 8**

Section 9.1, pages 3 through 6

**APPENDIX A**

pages 3 and 4

**INSERT PAGE(S)**

Section 9.1, pages 3 through 6

pages 3 and 4

- 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 in 32 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, TRICARE Management Activity (TMA) 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/pharmacy/unif\\_form.cfm](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 MCSC or responsible Military Treatment Facility (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 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 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.

- END -

# TRICARE Policy Manual 6010.57-M, February 1, 2008

## Appendix A

### Acronyms And Abbreviations

---

APN	Assigned Provider Number
APO	Army Post Office
ARB	Angiotensin Receptor Blocker
ARCIS	Archives and Records Centers Information System
ART	Assisted Reproductive Technology
ARU	Automated Response Unit
ARVC	Arrhythmogenic Right Ventricular Cardiomyopathy
ASA	Adjusted Standardized Amount American Society of Anesthesiologists
ASAP	Automated Standard Application for Payment
ASC	Accredited Standards Committee Ambulatory Surgical Center
ASCA	Administrative Simplification Compliance Act
ASCUS	Atypical Squamous Cells of Undetermined Significance
ASD	Assistant Secretary of Defense Atrial Septal Defect Autism Spectrum Disorder
ASD(C3I)	Assistant Secretary of Defense for Command, Control, Communications, and Intelligence
ASD(HA)	Assistant Secretary of Defense (Health Affairs)
ASD (MRA&L)	Assistant Secretary of Defense for Manpower, Reserve Affairs, and Logistics
ASP	Average Sale Price
ASRM	American Society for Reproductive Medicine
ATA	American Telemedicine Association
ATB	All Trunks Busy
ATO	Approval to Operate
AVM	Arteriovenous Malformation
AWOL	Absent Without Leave
AWP	Average Wholesale Price
B&PS	Benefits and Provider Services
B2B	Business to Business
BACB	Behavioral Analyst Certification Board
BBA	Balanced Budget Act
BBP	Bloodborne Pathogen
BBRA	Balanced Budget Refinement Act
BC	Birth Center
BCaBA	Board Certified Assistant Behavior Analyst
BCABA	Board Certified Associate Behavior Analyst
BCAC	Beneficiary Counseling and Assistance Coordinator
BCBA	Board Certified Behavior Analyst
BCBA-D	Board Certified Behavior Analyst - Doctoral
BCBS	Blue Cross [and] Blue Shield
BCBSA	Blue Cross [and] Blue Shield Association

**TRICARE Policy Manual 6010.57-M, February 1, 2008**

Appendix A

Acronyms And Abbreviations

---

BCC	Biostatistics Center
BE&SD	Beneficiary Education and Support Division
BH	Behavioral Health
BI	Background Investigation
BIA	Bureau of Indian Affairs
BIPA	Benefits Improvement Protection Act
BL	Black Lung
BLS	Basic Life Support
BMI	Body Mass Index
BMT	Bone Marrow Transplantation
BNAF	Budget Neutrality Adjustment Factor
BOS	Bronchiolitis Obliterans Syndrome
BP	Behavioral Plan
PPPV	Benign Paroxysmal Positional Vertigo
BPC	Beneficiary Publication Committee
BRAC	Base Realignment and Closure
BRCA	BReast CAncer (genetic testing)
BRCA1/2	BReast CAncer Gene 1/2
BS	Bachelor of Science
BSGI	Breast-Specific Gamma Imaging
BSID	Bayley Scales of Infant Development
BSR	Beneficiary Service Representative
BWE	Beneficiary Web Enrollment
C&A	Certification and Accreditation
C&P	Compensation and Pension
C/S	Client/Server
CA	Care Authorization
CA/NAS	Care Authorization/Non-Availability Statement
CABG	Coronary Artery Bypass Graft
CAC	Common Access Card
CACREP	Council for Accreditation of Counseling and Related Educational Programs
CAD	Coronary Artery Disease
CAF	Central Adjudication Facility
CAH	Critical Access Hospital
CAMBHC	Comprehensive Accreditation Manual for Behavioral Health Care
CAP	Competitive Acquisition Program
CAP/DME	Capital and Direct Medical Education
CAPD	Continuous Ambulatory Peritoneal Dialysis
CAPP	Controlled Access Protection Profile
CAQH	Council for Affordable Quality Health
CARC	Claim Adjustment Reason Code
CAS	Carotid Artery Stenosis