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TRICARE  
MANAGEMENT ACTIVITY

**MB&RB**

**CHANGE 77  
6010.57-M  
SEPTEMBER 18, 2012**

**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: TRICARE OFF-LABEL USES OF DEVICES**

**CONREQ:** 16096

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

**SUMMARY OF CHANGE(S):** This change allows cost-sharing of off-label uses of medical devices; clarifies how effective dates are determined for evolving technologies; clarifies coverage of off-label uses of drugs and biologics; and references the off-label drug and biologic policy in the Botox policy.

**EFFECTIVE DATE:** July 27, 2012.

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

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**ATTACHMENT(S): 13 PAGE(S)  
DISTRIBUTION: 6010.57-M**

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

**CHANGE 77**  
**6010.57-M**  
**SEPTEMBER 18, 2012**

**REMOVE PAGE(S)**

**CHAPTER 1**

Section 2.1, pages 1 - 3

**CHAPTER 7**

Section 27.1, pages 1 - 3

**CHAPTER 8**

Section 5.1, pages 1 and 2

Section 9.1, pages 3 - 6

**INSERT PAGE(S)**

Section 2.1, pages 1 - 3

Section 27.1, pages 1 - 3

Section 5.1, pages 1 - 3

Section 9.1, pages 3 - 6

## Unproven Drugs, Devices, Medical Treatments, And Procedures

Issue Date: November 1, 1983

Authority: [32 CFR 199.2](#) and [32 CFR 199.4\(g\)\(15\)](#)

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### 1.0 POLICY

By law, TRICARE can only cost-share medically necessary supplies and services. TRICARE regulations and program policies restrict benefits to those drugs, devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any drug, device, medical treatment, or procedure whose safety and efficacy has not been established is unproven and is excluded from coverage.

**2.0** A drug, device, medical treatment, or procedure is unproven:

**2.1** If the drug or device cannot be lawfully marketed without the approval or clearance of the U.S. Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient.

**2.2** If a medical device with an Investigational Device Exemption (IDE) approved by the FDA is categorized by the FDA as experimental/investigational (FDA Category A).

**2.3** Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis.

**2.4** If the reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis.

**3.0** This exclusion includes all services directly related to the unproven drug, device, medical treatment or procedure.

**4.0** Cost-sharing may be allowed for services or supplies when there is no logical or causal relationship between the unproven drug, device, treatment, or procedure and the treatment at

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

Chapter 1, Section 2.1

Unproven Drugs, Devices, Medical Treatments, And Procedures

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issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This cost-sharing is authorized in the following circumstances:

**4.1** Treatment that is not related to the unproven drug, device, treatment, or procedure; e.g., medically necessary treatment the beneficiary would have received in the absence of the unproven drug, device, treatment, or procedure.

**4.2** Treatment which is a necessary follow-up to the unproven drug, device, treatment, or procedure but which might have been necessary in the absence of the unproven treatment.

**5.0** In making a determination that a drug, device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice, TRICARE uses the following hierarchy of reliable evidence (see [32 CFR 199.2](#)):

**5.1** Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

**5.2** Published formal technology assessments.

**5.3** The published reports of national professional medical associations.

**5.4** Published national medical policy organization positions.

**5.5** The published reports of national expert opinion organizations.

**6.0** The hierarchy of reliable evidence of proven medical effectiveness, established by [paragraphs 5.1](#) through [5.5](#), is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

**7.0** TRICARE policy and benefit structure is never based solely that of other government medical programs, including Medicare, because each operates under its own statutes and regulations. Furthermore, while TRICARE may examine the policies of private third party payers. TRICARE coverage may only be based on governing statutes and regulations.

**8.0** The contractor(s) shall routinely review the hierarchy of reliable evidence, as defined in [32 CFR 199.2](#), and bring to TRICARE Management Activity's (TMA) attention drugs, devices, medical treatments, or procedures that they believe have moved from unproven to proven. TMA will apply the standards and procedures in TRICARE regulation and policy and if determined by TMA to have moved to proven, will notify all contractors that the drug, device, medical treatment, or procedure is proven and a part of the TRICARE benefit.

**9.0** For drugs, devices, medical treatments, and procedures that TRICARE has determined have moved from the status of unproven to the status of proven in accordance with the procedure

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

Chapter 1, Section 2.1

Unproven Drugs, Devices, Medical Treatments, And Procedures

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established in [paragraph 5.0](#), the effective date (or the date on which the particular drug, device, medical treatment, or procedure may be cost-shared) is the date published reliable evidence (as described in [32 CFR 199.2](#)) shows proven medical effectiveness. For example, the effective date may be established as the date of publication of a well-controlled study of clinically meaningful endpoints published in refereed medical literature, or the publication date of a formal technology assessment.

**Note:** See [Section 3.1](#) for policy on Rare Diseases.

**Note:** See [Chapter 7, Section 24.1](#) for policy on cancer clinical trials.

**Note:** See [Chapter 8, Section 5.1](#) for policy on medical devices, including coverage of **off-label uses of medical devices**, Humanitarian Use Devices and a FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B).

**Note:** See [Chapter 8, Section 9.1](#) for policy on off-label use of drugs.

- END -



## Botulinum Toxin Injections

Issue Date: October 12, 1998

Authority: [32 CFR 199.4\(c\)\(2\)\(iii\)](#) and [\(c\)\(2\)\(iv\)](#)

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### 1.0 CPT<sup>1</sup> PROCEDURE CODES

46505, 64611 - 64614, 64640, 64653, 67345

### 2.0 HCPCS PROCEDURE CODES

J0585, J0587

### 3.0 DESCRIPTION

These procedures involve the injection of small amounts of botulinum toxin into selected muscles for the nonsurgical treatment of the conditions relating to spasticity, various dystonias, nerve disorders, and muscular tonicity deviations.

### 4.0 POLICY

**4.1** Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA) and Botulinum toxin B (RimabotulinumtoxinB) injections may be considered for cost-sharing for treating conditions such as cervical dystonia (repetitive contraction of the neck muscles) in decreasing the severity of abnormal head position and neck pain for patients 16 years and older.

**4.2** Botulinum toxin A (OnabotulinumtoxinA) injections may be considered for cost-sharing for treating conditions such as blepharospasm (spasm of the eyelids/uncontrolled blinking) and strabismus (squinting/eyes do not point in the same direction) associated with dystonia, including benign essential blepharospasm or VII nerve disorders for patients 12 years of age and older.

**4.3** Botulinum toxin A (OnabotulinumtoxinA) injections may be considered for cost-sharing for treating conditions such as severe primary axillary hyperhidrosis (severe underarm sweating) that is inadequately managed by topical agents for patients 18 years of age and older.

**4.4** Botox<sup>®</sup> (OnabotulinumtoxinA-chemodenervation-CPT<sup>1</sup> procedure code 46505) may be considered for off-label cost-sharing for the treatment of chronic anal fissure unresponsive to conservative therapeutic measures, effective May 1, 2007.

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**4.5** Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA) injections may be considered for off-label cost-sharing for the treatment of spasticity resulting from Cerebral Palsy (CP), effective November 1, 2008.

**4.6** Botox® (OnabotulinumtoxinA) and Myobloc® (RimabotulinumtoxinB) injections may be considered for Off-label cost-sharing for the treatment of sialorrhea associated with Parkinson disease patients who are refractory to, or unable to tolerate, systemic anticholinergics, effective October 1, 2009.

**4.7** Botulinum toxin A (OnabotulinumtoxinA) injections for prophylaxis of headaches in adult patients with chronic migraine, which is defined as 15 days or more per month with headache lasting four hours a day or longer.

**4.8** Botulinum toxin A (OnabotulinumtoxinA) injections to treat spasticity in flexor muscles of the elbow, wrist, and fingers (upper limb spasticity) in adults.

**4.9** Botulinum toxin A (OnabotulinumtoxinA) injections for laryngeal dystonia (adductor spasmodic dysphonia) and oromandibular dystonia (jaw-closing dystonia) may be considered for cost-sharing.

**4.10** Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA) and Botulinum toxin B (Rimabotulinumtoxin B) injections may be considered for cost-sharing for FDA approved indications, unless otherwise excluded by the program.

**4.11** Off-label use. Effective July 27, 2012, off-label uses of Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA) and Botulinum toxin B (Rimabotulinumtoxin B) injections may be approved for cost-sharing by the contractor in accordance with Chapter 8, Section 9.1, paragraph 2.2.5.

## **5.0 EXCLUSIONS**

**5.1** Botulinum toxin A injections are unproven for the following indications:

- Palmar hyperhidrosis.
- Urinary urge incontinence.
- Lower back pain/lumbago.
- Episodic migraine, chronic daily headache, cluster headache, cervicogenic headache, and tension-type headache.

**5.2** Botox® (OnabotulinumtoxinA-chemodenervation-CPT<sup>2</sup> procedure code 64612) for the treatment of muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis is unproven.

**5.3** Botox® (OnabotulinumtoxinA) used for cosmetic indications (e.g., frown lines and brow furrows) is excluded from coverage.

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

Chapter 7, Section 27.1

Botulinum Toxin Injections

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**6.0 EFFECTIVE DATES**

**6.1** May 1, 2007, for coverage of chronic anal fissure unresponsive to conservative therapeutic measures (CPT<sup>2</sup> procedure code 46505).

**6.2** October 1, 2009, for coverage of sialorrhea associated with Parkinson disease patients who are refractory to, or unable to tolerate, systemic anticholinergics (CPT<sup>2</sup> procedure code 64653). Effective January 1, 2011, use CPT<sup>2</sup> procedure code 64611.

**6.3** October 15, 2010, coverage for prophylaxis of headaches in adult patients with chronic migraine, which is defined as 15 days or more per month with headache lasting four hours a day or longer.

**6.4** March 9, 2010, coverage for spasticity in flexor muscles of the elbow, wrist, and fingers (upper limb spasticity) in adults.

**6.5** November 14, 1990, coverage for laryngeal dystonia (adductor spasmodic dysphonia) and oromandibular dystonia (jaw-closing dystonia).

- END -



## Chapter 8

## Section 5.1

# Medical Devices

Issue Date: December 18, 1992

Authority: [32 CFR 199.2\(b\)](#), [32 CFR 199.4\(a\)](#), [\(b\)](#), [\(c\)](#), and [\(g\)\(15\)](#)

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### 1.0 DESCRIPTION

**1.1** Section 201(h) of the Food, Drug and Cosmetic Act defines medical devices as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

**1.1.1** Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;

**1.1.2** Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or

**1.1.3** Intended to affect the structure of any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

**1.2** Devices which meet this definition are regulated by the U.S. Food and Drug Administration (FDA) and are subject to premarketing and postmarketing regulatory controls. (For further information see the FDA's web site: <http://www.fda.gov>.)

### 2.0 POLICY

**2.1** Medical devices may be covered when medically necessary, appropriate, the standard of care, and not otherwise excluded.

**2.2** Medical devices must be FDA approved or of a type not requiring pre-market approval by the FDA. Not all of these (either FDA approved or those not requiring pre-market approval) are covered. Not all FDA approved devices are covered. Coverage of a medical device is subject to all other requirements of the law, rules, and policy governing TRICARE. If the device is used for a noncovered or excluded indication, benefits may not be allowed. For example, tinnitus masker is an FDA approved device; however, TRICARE considers this device unproven and, therefore, not a benefit.

**2.3** Effective July 27, 2012, coverage may be considered for off-label uses of devices.

**2.3.1** Off-label uses of devices 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.

**2.3.2** Approval for reimbursement of off-label uses of devices shall be provided by the contractor. The contractor 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 device is safe, effective and in accordance with nationally accepted standards of practice in the medical community. If the device is FDA approved and the off-label use is medically necessary, supported by medical literature identified by the contractor, which indicates the device is nationally accepted as standard practice, and is not otherwise excluded, the contractor may approve the cost-sharing for the off-label medical device.

**2.4** A humanitarian use device approved for marketing through a Humanitarian Device Exemption application may be covered. Coverage of any such device is subject to all other requirements of the law, rules, and policy governing TRICARE.

**2.5** TRICARE will consider for coverage a device with an FDA approved Investigational Device Exemption (IDE) categorized by the FDA as non-experimental/investigational (FDA Category B) for beneficiaries participating in FDA approved clinical trials. Coverage of any such Category B device is dependent on its meeting all other requirements of the law, rules, and policy governing TRICARE and upon the beneficiary involved meeting FDA approved IDE study protocols.

**2.6** Devices with a FDA approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B), which was the subject of an FDA approved clinical trial(s), may be considered for coverage once it receives FDA approval for commercial marketing. Coverage is dependent on the device meeting the FDA requirements/conditions of approval and all other requirements governing TRICARE.

### **3.0 EXCLUSION**

**3.1** Experimental/Investigational (Category A) IDEs.

**4.0 EFFECTIVE DATES**

**4.1** Device used for an FDA approved application. Effective date is the date of the FDA approval.

**4.2** Category B IDEs. Effective date is the date the device is classified as a Category B device by the FDA.

**4.3** Off-label uses of medical devices. Effective date is July 27, 2012.

- END -



- 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** 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.

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

### Chapter 8, Section 9.1

#### Pharmacy Benefits Program

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**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 -