



TRICARE
MANAGEMENT ACTIVITY

MB&RB

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS

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**CHANGE 166
6010.54-M
SEPTEMBER 18, 2012**

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE POLICY MANUAL (TPM), AUGUST 2002**

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

CHANGE TITLE: TRICARE OFF-LABEL USES OF DEVICES

CONREQ: 16095

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): 12 PAGE(S)
DISTRIBUTION: 6010.54-M**

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

CHANGE 166
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REMOVE PAGE(S)

CHAPTER 1

Section 2.1, pages 3 through 5

CHAPTER 7

Section 27.1, pages 1 through 3

CHAPTER 8

Section 5.1, pages 1 and 2

Section 9.1, pages 3 through 5

INSERT PAGE(S)

Section 2.1, pages 3 through 5

Section 27.1, pages 1 through 3

Section 5.1, pages 1 through 3

Section 9.1, pages 3 through 5

I. 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 established in [paragraph I.E.](#), 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.

J. The following is a partial list of drugs, devices, medical treatments, or procedures considered to be unproven. Other drugs, devices, medical treatments, or procedures also considered to be unproven are listed as specific exclusions in relevant sections of the TRICARE Policy Manual ([TPM](#)). For example, Cardiomyoplasty for treatment of heart failure is considered unproven and is listed as a specific exclusion in [Chapter 4, Section 9.1](#) (Cardiovascular System). Neither the partial list below nor the exclusions cited in other sections of the [TPM](#) provide an all inclusive list of unproven drugs, devices, medical treatments, or procedures. Other unproven drugs, devices, medical treatments, or procedures are also excluded although they do not appear in the [TPM](#).

1. Adoptive immunotherapy using either Tumor-Infiltrating Lymphocytes (TIL) or Lymphokine-Activated Killer (LAK) cells, activated in vitro by recombinant or natural IL-2 or other lymphokines, for the treatment of cancer.
2. Adrenal tissue transplant to brain.
3. Autolymphocyte Therapy (ALT).
4. Calcium EAP/calcium orotate and selenium (also known as Nieper therapy) - involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, multiple sclerosis -- Not a proven treatment for any indication.
5. Canaloplasty in the treatment of glaucoma is unproven.
6. Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis are unproven (i.e., allergenic extracts of *Candida albicans* for immunotherapy and/or provocation/neutralization). Disseminated systemic candidiasis (ICD-9-CM 112.5) is a recognized diagnosis, and medically necessary treatment is covered.
7. Cellular therapy (HCPCS procedure code M0075).
8. Chelation therapy, except when using FDA-approved chelators for FDA-approved indications.
9. Diaphanography (Transillumination Light Scanning).

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CHAPTER 1, SECTION 2.1

UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

10. Dynamic Posturography (both static and computerized) (CPT¹ procedure code 92548).
11. Electric reflex salivary stimulation (Salitron® Electrostimulation System) in the treatment of xerostomia (dry mouth) secondary to Sjogren's syndrome (HCPCS procedure code E0755).
12. Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procuren®, a platelet-derived wound-healing formula.
13. Hand transplant from a cadaver donor.
14. Histamine therapy.
15. Holding therapy - involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks.
16. Hyperosmotic blood-brain barrier disruption produced by infusion of Mannitol to increase drug delivery to brain tumors.
17. Hyperventilation Provocation Test (HVPT) for diagnosing hyperventilation syndrome.
18. Immunotherapy for malignant disease except when using drugs approved by the FDA for this purpose.
19. Intracavitary administration of cisplatin for malignant disease is unproven, except for patients with optimally debulked Stage III ovarian cancer and pseudomyxoma peritonei resulting from appendiceal carcinoma.
20. Iridology (links flaws in eye coloration with disease elsewhere in the body).
21. Light therapy for Seasonal Depression (also known as seasonal affective disorder (SAD)). This therapy uses varying degrees of light to treat depression.
22. Neurofeedback.
23. All organ transplants not listed as covered in the [TPM](#) or [32 CFR 199.4\(e\)\(5\)](#).
24. Portable nocturnal hypoglycemia monitors.
25. Pupillometry.
26. Sensory Afferent Stimulation (SAS) devices for relief of nausea (e.g., Relief Band®).

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CHAPTER 1, SECTION 2.1

UNPROVEN DRUGS, DEVICES, MEDICAL TREATMENTS, AND PROCEDURES

27. Spinoscopy. Use of a Spinoscope with skin markers to assess the function of the spine.
28. Synaptic 2000 for acute and chronic pain.
29. Tinnitus Masker.
30. Transdermal nicotine therapy used to treat ulcerative colitis.
31. Transfer Factor (TF). This is a Dialyzable Leukocyte Extract (DLE) used to transfer delayed hypersensitivity from an immune to a nonimmune subject and is considered unproven.

NOTE: See [Chapter 1, 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 Investigational Device Exemption (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)

I. CPT¹ PROCEDURE CODES

46505, 64611 - 64614, 64640, 64653, 67345

II. HCPCS PROCEDURE CODES

J0585, J0587

III. 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.

IV. POLICY

A. 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.

B. 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.

C. 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.

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D. Botox® (OnabotulinumtoxinA-chemodenervation-CPT² 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.

E. 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.

F. 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.

G. 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.

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

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

J. 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.

K. 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 II.C.2..

V. EXCLUSIONS

A. Botulinum toxin A injections are unproven for the following indications:

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

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CHAPTER 7, SECTION 27.1

BOTULINUM TOXIN INJECTIONS

B. Botox® (OnabotulinumtoxinA-chemodenervation-CPT³ procedure code 64612) for the treatment of muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis is unproven.

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

VI. EFFECTIVE DATES

A. May 1, 2007, for coverage of chronic anal fissure unresponsive to conservative therapeutic measures (CPT³ procedure code 46505).

B. October 1, 2009, for coverage of sialorrhea associated with Parkinson disease patients who are refractory to, or unable to tolerate systemic anticholinergics (CPT³ procedure code 64653). Effective January 1, 2011, use CPT³ procedure code 64611.

C. 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.

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

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

- END -

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MEDICAL DEVICES

ISSUE DATE: December 18, 1992

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

I. DESCRIPTION

A. 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. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
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
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.

B. Devices which meet this definition are regulated by the 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>.)

II. POLICY

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

B. Medical devices must be FDA approved. 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.

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

1. Off-label 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. 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.

D. 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.

E. 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.

F. 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.

III. EXCLUSION

Experimental/Investigational (Category A) IDEs.

IV. EFFECTIVE DATES

A. Device used for an FDA-approved application. Effective date is the date of the FDA approval.

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

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

- END -

C. General Prescription Coverage

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

- a. The drug is approved for marketing by the **FDA**;
- 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. **Coverage** may be **considered** for off-label uses of drugs and biologics.

- a. **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.

b. 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](#) and the TOP contract.

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.

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CHAPTER 8, SECTION 9.1 PHARMACY BENEFITS PROGRAM

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 (**NDAA**), 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 **FDA** 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 (**TRM**). Beneficiaries shall pay a co-pay in accordance with [Chapter 12, Section 11.1](#) or **TRM, 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.

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CHAPTER 8, SECTION 9.1

PHARMACY BENEFITS PROGRAM

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 **medical literature as described in paragraph II.C.2.** establishes the safety and efficacy of the drug for that specific use.

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

- END -

