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DEPARTMENT OF DEFENSE

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Office of the Secretary

32 CFR Part 199

DOD-2008-HA-0090

RIN 0720-AB23

TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, Medical Treatments, or Procedures

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Department of Defense is publishing this final rule to revise the definition of “unlabeled or off-label drug” to “off-label use of a drug or device.” This provision codifies the coverage of those medically necessary indications for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe and effective and in accordance with nationally accepted standards of practice in the medical community. Additionally, this rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed in TRICARE regulations. We are removing the partial list from the regulation but will maintain the partial list in the TRICARE Policy Manual at www.tricare.mil.

EFFECTIVE DATE: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Ms. Elan Green, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676-3907.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 31, 2009 (74 FR 44797-44798), the Office of the Secretary of Defense published for public comment a proposed rule that revised the definition of “unlabeled or off-label drug” to “off-label use of a drug or device.” In addition this proposed rule removed the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under Section 199.4(g)(15).

Off-Label Uses of Devices

On January 6, 1997, the Office of the Secretary of Defense published a final rule in the Federal Register (62 FR 627-631) clarifying the TRICARE exclusion of unproven drugs, devices, and medical treatments or procedures and adding the TRICARE definition of unlabeled or off-label drugs. This rule also added the provision for coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are prescribed or administered by a health care practitioner and are used for indications or treatments not included in the approved labeling. We are now modifying the definition of “unlabeled or off-label drug” to “off-label use of a drug or device,” which includes a drug, biologic or device under the regulatory authority of the FDA. However, this proposed rule does not present new agency policy. Rather, it corrects an error and omission from the current rule. Coverage is limited to those indications for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe and effective and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity.

In general, good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices, including combination products, according to their best knowledge and judgment. When providers use a product for an indication not in the approved labeling, they have a responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence. Limiting CHAMPUS cost-sharing to those off-label uses for which there are demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community will help to ensure there is sufficient scientific evidence supporting the off-label use, without being overly onerous, while still promoting innovations in medical practice that benefit patients.

In reviewing the proposed rule, we discovered that we had inadvertently incorporated the TRICARE reliable evidence standard (as defined in 32 CFR 199.2) as the threshold for reviewing coverage for off-label or unlabeled use. The intent was not to make the standard of review more onerous but rather to expand the application of the existing provision regarding the cost-sharing of off-label use of drugs to also include the off-label use of devices and biologics. As a result, we are withdrawing the changes to the third paragraph of the Note to paragraph (g)(15)(i)(A) in section 199.4 with the exception of replacing the term “unlabeled or off-label uses of drugs” with “off-label uses of drugs and devices,” with an appropriate reference back to the definition of the term in 199.2. “Off-label uses of drugs and devices” includes off-label uses of drugs, biologics, devices, and combination products.

Although most biological products meet the definition of “drugs” under the Federal Food, Drug and Cosmetic Act, and are also regulated under that law, biological products are approved for marketing under the Public Health Services Act by means of a biologics license application.

Thus, the definition of “off-label use of a drug or device” has been revised to acknowledge both the Federal Food, Drug and Cosmetic Act and the Public Health Services Act as sources of the FDA’s regulatory authority over the marketing of these products.

Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

By law, TRICARE can cost-share only medically necessary supplies and services. Any drug, device, and medical treatment or procedure, the safety and efficacy of which have not been established, as described in Part 199.4(g)(15), is unproven and cannot be cost-shared by TRICARE except as authorized under paragraph 199.4(e)(26). The current regulation and program policy provide a partial list of examples of unproven drugs, devices, and medical treatments or procedures that are excluded from benefits. The intent of this partial list was to provide information on specific examples of emerging drugs, devices, and medical treatments or procedures determined to be unproven by TRICARE based on review of current reliable evidence. Due to the rapid and extensive changes in medical technology it is not feasible to maintain this list in the regulation. Removal of this partial list of examples does not change the exclusion of unproven drugs, devices, and medical treatments or procedures. Removal of the partial list of examples does not change the process TRICARE follows in determining for purposes of benefit coverage when a drug, device, and medical treatment or procedure has moved from the status of unproven to proven medical effectiveness. The intent of this revision is to ensure that benefit determinations are made based on current reliable evidence rather than relying on outdated regulatory and policy provisions. A partial list of unproven drugs, devices, medical treatments, or procedures will continue to be published in the TRICARE Policy Manual at www.tricare.mil.

II. Public Comments

We provided a 60-day public comment period following publication of the Proposed Rule in the Federal Register (74 FR 44797-44798) on August 31, 2009. We received no public comments.

III. Regulatory Procedures.

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Section 801 of title 5, United States Code, and Executive Orders 12866 and 13563 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of EOs 12866 and 13563.

Section 202, Public Law 104-4, “Unfunded Mandates Reform Act”

Section 202 of Public Law 104-4, “Unfunded Mandates Reform Act,” requires that an analysis be performed to determine whether any federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The "Regulatory Flexibility Act" (RFA) requires each Federal agency to prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This rule will not significantly impact a substantial number of small entities for purposes of the RFA.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511).

Executive Order 13132, "Federalism"

This rule has been examined for its impact under E.O. 13132 and does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government; therefore, consultation with the State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199--[AMENDED]

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.2(b) is amended by removing the definition of “Unlabeled or Off-label drugs” and adding a new definition of “Off-label use of a drug or device” in alphabetical order to read as follows:

§199.2 Definitions.

* * * * *

(b) * * *

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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.

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3. Section 199.4 is amended by revising the third paragraph of the Note to paragraph (g)(15)(i)(A), and removing paragraph (g)(15)(iv) as follows:

§ 199.4 Basic program benefits.

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(g) * * *

(15) * * *

(i) * * *

(A) * * *

Note: * * *

CHAMPUS will consider coverage of off-label uses of drugs and devices that meet the definition of Off-Label Use of a Drug or Device in § 199.2(b). Approval for reimbursement of off-label uses requires review for medical necessity and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use of the drug or device is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

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DATED: June 20, 2012.

Patricia L. Toppings

OSD Federal Register Liaison Officer

Department of Defense

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