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)
Revision:

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 shall 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 shall 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

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.

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