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)

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. Use of FDA-approved devices for off-label or non-FDA approved applications may be covered if documented by reliable evidence as safe, effective, and in accordance with nationally accepted standards of practice in the medical community. Coverage is subject to

all other requirements of the law, rules, and policy governing TRICARE. (See 32 CFR 199.2(b) or Chapter 1, Section 2.1 for the definition of reliable evidence.)

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. EXCLUSIONS

A. Experimental/Investigational (Category A) IDEs.

B. Off-label or non-FDA approved applications which are not documented as safe, effective and in accordance with nationally accepted standards of practice in the medical community.

IV. EFFECTIVE DATE

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

B. Device used for a non-FDA approved application - Effective date is the date the reliable evidence supports the application is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

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

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