

### Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

#### § 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

*Class I* refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

*Class II* refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

*Class III* refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

*Contractors* refers to carriers, fiscal intermediaries, and other entities that contract with CMS to review and adjudicate claims for Medicare services.

*Experimental/investigational (Category A) device* refers to an innovative device believed to be in Class III for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

*IDE* stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

*Non-experimental/investigational (Category B) device* refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

*PMA* stands for “premarket approval” and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

*Sponsor* refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

#### § 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

#### § 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

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(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at §411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

### § 405.207 Services related to a non-covered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not “reasonable” and “necessary” under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care services related to experimental/investigational (Category A) devices as defined in §405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

(3) Routine care services related to a non-experimental/investigational (Category B) device defined in §405.201(b)

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that is furnished in conjunction with an FDA-approved clinical trial.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004]

### § 405.209 Payment for a non-experimental/investigational (Category B) device.

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

### § 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device’s use.

### § 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor