

§ 405.203 FDA categorization of investigational devices.

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

(1) Category A (Experimental) devices.

(2) Category B (Nonexperimental/investigational) devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

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

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013]

§ 405.205 Coverage of a Category B (Nonexperimental/investigational) device.

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

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

(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.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013]

§ 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 contemporarily

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 items and services related to Category A (Experimental) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

(3) Routine care items and services related to Category B (Nonexperimental/investigational) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004; 78 FR 74809, Dec. 10, 2013]

§ 405.209 Payment for a Category B (Nonexperimental/investigational) device.

Payment under Medicare for a Category B (Nonexperimental/investigational) 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.

[78 FR 74809, Dec. 10, 2013]

§ 405.211 Coverage of items and services in FDA-approved IDE studies.

(a) *Coverage of routine care items and services for Category A (Experimental) devices.* Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.

(b) *Coverage of Category B (Nonexperimental/investigational) IDE devices and routine care items and services.* Medicare may make payment for a Category B (Nonexperimental/investigational) IDE