

Centers for Medicare & Medicaid Services, HHS

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AUTHORITY: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

Subpart A [Reserved]

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 Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

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

Category A (Experimental) device refers to a device 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.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial 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 premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health’s National Library of Medicine’s online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national non-coverage decision) that are furnished during a clinical study and that would

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be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013; 86 FR 3009, Jan. 14, 2021; 86 FR 62958, Nov. 15, 2021]

§ 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 “nec-

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essary” 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 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 device and routine care items and services furnished in an FDA-approved Category B (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria in § 405.212 are met.

(c) CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in § 405.212 are met for purposes of coverage of items and services described in paragraphs (a) and (b) of this section:

- (1) FDA approval letter of the IDE.
- (2) IDE study protocol.
- (3) IRB approval letter.
- (4) NCT number.
- (5) Supporting materials, as needed.

(d) *Notification.* A listing of all CMS-approved Category A (Experimental) IDE studies and Category B (Nonexperimental/investigational) IDE studies shall be posted on the CMS Web site and published in the FEDERAL REGISTER.

[78 FR 74809, Dec. 10, 2013]

§ 405.212 Medicare Coverage IDE study criteria.

(a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:

- (1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
- (2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- (3) The study results are not anticipated to unjustifiably duplicate existing knowledge.
- (4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate

to confidently answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of successfully completing the study.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812 and 45 CFR part 46.

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

(8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

(b) [Reserved]

[78 FR 74809, Dec. 10, 2013]

§ 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 Category A (experimental) 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

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in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74810, Dec. 10, 2013]

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

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EDITORIAL NOTE: Nomenclature changes to subpart C of part 405 appear at 76 FR 5961, Feb. 2, 2011.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person must, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in