Centers for Medicare & Medicaid Services, HHS § 405.213

preparation for the use of a noncovered device, services furnished contempo-

raneously 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 di-

agnosis, monitoring or treatment of an immediately life-threatening disease or

condition.

(b) Potentially covered non-experimental/investigational (Category B) de-

vices. Medicare contractors may approve coverage for any device with an

FDA-approved IDE categorized as a non-experimental/investigational (Cat-

ey A) 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
do not agree with an FDA decision
that categorizes its device as experi-

mental/investigational (Category A)
may request re-evaluation of the cat-
ergORIZATION 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 de-
scribed in paragraphs (b) and (c) of this
section are available to the sponsor.

(4) Neither the FDA original cat-
ergORIZATION or re-evaluation (described
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 cat-
ergORIZATION 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 ob-
tains 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 rec-
ommendation. CMS reviews only infor-
mation in the FDA record to determine
whether to change the categorization