§ 405.203 (a)(2) and (b); and by adding par-
paragraph (a)(3), effective Jan. 1, 2015. For the convenience of the user, the added and re-
vised text is set forth as follows:

§ 405.201 Scope of subpart and definitions.

(a) * * *
(2) CMS may consider for Medicare cov-
erage certain devices with an FDA-approved
investigational device exemption (IDE) that
have been categorized as Category B (Non-
experimental/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 de-
vice type has not been established (that is,
initial questions of safety and effectiveness
have not been resolved) and the FDA is un-
sure whether the device type can be safe and
effective.
Category B (Nonexperimental/investiga-
tional) device refers to a device for which the incre-
mental risk is the primary risk in question
(that is, initial questions of safety and effec-
tiveness of that device type have been re-
olved), or it is known that the device type
can be safe and effective because, for ex-
ample, other manufacturers have obtained FDA
premarket approval or clearance for that de-
vice type.
ClinicalTrials.gov refers to the National Insti-
tutes of Health’s National Library of
Medicine’s online registry and results data-
base of publicly and privately supported clinical
studies of human participants conducted
around the world.
Contractors refers to Medicare Administra-
tive Contractors and other entities that con-
tract 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 con-
ducting a clinical study in accordance with
Routine care items and services refers to
items and services that are otherwise gen-
erally available to Medicare beneficiaries
(that is, a benefit category exists, it is not
statutorily excluded, and there is no na-
tional noncoverage decision) that are fur-
nished during a clinical study and that
would be otherwise furnished even if the ben-
eficiary were not enrolled in a clinical study.

§ 405.203 FDA categorization of inves-
tigational devices.

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

(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/in-
vestigational (Category A) or non-ex-
perimental/investigational (Category
B).

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

Effective Date Note: At 78 FR 74809,
Dec. 10, 2013, §405.203 was amended by revising
paragraphs (a)(1) and (2) and (b), effective
Jan. 1, 2015. For the convenience of the user,
the revised text is set forth as follows:

§ 405.203 FDA categorization of investiga-
tional devices.

(a) * * *
(1) Category A (Experimental) devices.
(2) Category B (Nonexperimental) 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).

* * * * *

§ 405.205 Coverage of a non-experi-
tmental/investigational (Category B)
device.

(a) For any device that meets the re-
quirements 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 non-exper-
imental/investigational (Category B).

(2) CMS uses the categorization of
the device as a factor in making Medi-
care 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 no-
tifies the sponsor and CMS and the pro-
cedures described in paragraph (a)(2) of
this section apply.

Effective Date Note: At 78 FR 74809,
Dec. 10, 2013, §405.205 by revising the section head-
ing and paragraph (a)(1), effective Jan. 1,
2015. For the convenience of the user, the re-
vised text is set forth as follows:

116