Centers for Medicare & Medicaid Services, HHS § 419.64

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

(a) Eligibility for pass-through payment. CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) Orphan drugs. A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) Cancer therapy drugs and biologicals. A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) Radiopharmaceutical drugs and biological products. A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) Other drugs and biologicals. A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under §419.32(c)) as defined in paragraph (b) of this section.

(iii) A biological that is not surgically implanted or inserted into the body.

(iv) A biological that is surgically implanted or inserted into the body, for which pass-through payment as a biological is made on or before December 31, 2009.

(b) Cost. CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) Services furnished before January 1, 2003. The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) Services furnished after December 31, 2002. CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the related service by at least 25 percent.

(ii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug
or biological exceeds 10 percent of the
APC payment amount for the related
service.
(c) Limited period of payment. CMS
limits the eligibility for a pass-through
payment under this section to a period
of at least 2 years, but not more than
3 years, that begins as follows:
(1) For a drug or biological described
in paragraphs (a)(1) through (a)(3) of
this section—August 1, 2000.
(2) For a drug or biological described
in paragraph (a)(4) of this section—the
date that CMS makes its first pass-
through payment for the drug or bio-
logical.
(d) Amount of pass-through payment.
Subject to any reduction determined
under §419.62(b), the pass-through pay-
ment for a drug or biological equals the
amount determined under section
1842(o) of the Social Security Act,
minus the portion of the APC payment
amount that CMS determines is associ-
ated with the drug or biological.

§419.66 Transitional pass-through pay-
ments: Medical devices.
(a) General rule. CMS makes a pass-
through payment for a medical device
that meets the requirements in para-
graph (b) of this section and that is de-
scribed by a category of devices estab-
lished by CMS under the criteria in
paragraph (c) of this section.
(b) Eligibility. A medical device must
meet the following requirements:
(1) If required by the FDA, the device
must have received FDA approval or
clearance (except for a device that has
received an FDA investigational device
exemption (IDE) and has been classi-
fied as a Category B device by the FDA
in accordance with §§405.203 through
405.207 and 405.211 through 405.215 of
this chapter) or another appropriate
FDA exemption.
(2) The device is determined to be
reasonable and necessary for the diag-
osis or treatment of an illness or in-
jury or to improve the functioning of a
malformed body part (as required by
section 1862(a)(1)(A) of the Act).
(3) The device is an integral and sub-
ordinate part of the service furnished,
is used for one patient only, comes in
contact with human tissue, and is sur-
gically implanted or inserted whether
or not it remains with the patient
when the patient is released from the
hospital.
(4) The device is not any of the fol-
lowing:
(i) Equipment, an instrument, appa-
ratus, implement, or item of this type
for which depreciation and financing
expenses are recovered as depreciable
assets as defined in Chapter 1 of the
Medicare Provider Reimbursement
Manual (CMS Pub. 15-1).
(ii) A material or supply furnished in-
cident to a service (for example, a su-
ture, customized surgical kit, or clip,
other than radiological site marker).
(iii) A material that may be used to
replace human skin (for example, a bio-
logical skin replacement material or
synthetic skin replacement material).
(c) Criteria for establishing device cat-
egories. CMS uses the following criteria
to establish a category of devices under
this section:
(1) CMS determines that a device to
be included in the category is not ap-
propriately described by any of the ex-
isting categories or by any category
previously in effect, and was not being
paid for as an outpatient service as of
December 31, 1996.
(2) CMS determines that a device to
be included in the category has dem-
onstrated that it will substantially im-
prove the diagnosis or treatment of an
illness or injury or improve the func-
tioning of a malformed body part com-
pared to the benefits of a device or de-
vices in a previously established cat-
egory or other available treatment.
(3) Except for medical devices identi-
fied in paragraph (e) of this section,
CMS determines the cost of the device
is not insignificant as described in
paragraph (d) of this section.
(d) Cost criteria. CMS considers the
average cost of a category of devices to
be not insignificant if it meets the fol-
lowing conditions:
(1) The estimated average reasonable
cost of devices in the category exceeds
25 percent of the applicable APC pay-
ment amount for the service related to
the category of devices.
(2) The estimated average reasonable
cost of the devices in the category ex-
ceeds the cost of the device-related