§ 419.62 Transitional pass-through payments: General rules.

(a) General. CMS provides for additional payments under §§419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) Budget neutrality. CMS establishes the additional payments under §§419.64 and 419.66 in a budget neutral manner.

(c) Uniform prospective reduction of pass-through payments. (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2)) of the total amount of Medicare payments under the outpatient prospective payment system, CMS will reduce, pro rata, the amount of each of the additional payments under §§419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

§ 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:
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§ 419.66 Transitional pass-through payments: Medical devices.

(a) General rule. CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices established 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 classified 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 diagnosis or treatment of an illness or injury 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 subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically 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 following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable