Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System

Please note: For process and information required to apply for transitional pass-through payment status for **drugs and nonimplantable biologicals**, or for assignment and payment for **new technology service APCs**, go to the main OPPS web page, currently at http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp#TopOfPage to see the latest instructions. (NOTE: Due to the continuing development of the cms.hhs.gov web site, references to links herein may change.) As of January 1, 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or natural orifice) are being evaluated for device pass-through payment under the instructions contained herein, using the device pass-through process. Therefore, when referring to the device application process and information requirements in this document, implantable biologicals are also included.

GENERAL APPLICATION PROCESS FOR ADDITIONAL DEVICE CATEGORIES

This guidance describes in detail the process and information required for applications requesting additional categories for medical devices that may be eligible for transitional pass-through payment under the Medicare hospital outpatient prospective payment system (OPPS). These instructions apply solely to requests for ***additional categories of medical devices for pass-through payment.***

Refer to the interim final rule with comment period in the November 2, 2001 *Federal Register* and the final rule with comment period in the November 1, 2002 *Federal Register* (67 FR 66781) and the modifications to certain criteria in the November 10, 2005 (70 FR 68628) final rule with comment period for a full discussion of the criteria for establishing additional pass-through categories for medical devices. These rules can currently be found at http://www.cms.gov/HospitalOutpatientPPS. Refer to the November 20, 2009 Federal Register (74 FR 60471) for modifications to the pass-through process for implantable biological products.

Because CMS intends to make information used in the ratesetting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

We will accept transitional pass-through applications for additional categories for medical devices on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which transitional pass-through payment is sought to allow time for analysis, decision-making, and systems changes. The table below indicates the earliest date that pass-through status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the first business date in:	**Earliest Possible Date For Pass-Through Status to be Effective:**
March	July 1
June	October 1
September	January 1
December	April 1

PLEASE NOTE: Pass-through status may or may not be effective on earliest possible effective date as described above. A longer evaluation period may be required if an application is incomplete, if further information is required, if a more extensive evaluation is required in order to determine eligibility, or due to other factors.

An application is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

We can act only on applications that fully address the criteria and requirements set forth in this announcement.

Who may apply?

Device or implantable biological manufacturers, hospitals, or other interested parties may apply for a new device category for transitional pass-through payments.

Can a device be included in more than one category?

No. The law requires that new categories be established in such a way that no medical device is described by more than one category.

Are there cost requirements for devices in new categories?

The law requires that the average cost of devices included in a new category be "not insignificant" relative to the payment amount for the procedure(s) or service(s) with which the device is associated. The definition of "not insignificant" cost is described below and also in the November 2, 2001 interim final rule.

How are combination products evaluated?

For combination products (e.g., a product that has a device component and a drug component) CMS initially evaluates the product to determine which component is the key therapeutic or diagnostic component, similar to FDA's "primary mode of action" determination for assignment to a lead center with primary jurisdiction. However, our key component determination may be different from FDA's primary mode of action determination. After this initial evaluation we then evaluate the item under the device or drug and biological pass-through process, as appropriate. For example, if the key component of the candidate pass-through product is a biological and that biological is only "implanted" because it is administered through an implanted delivery system for the biological (that is, the biological itself is not functioning as an implantable device), then we would evaluate the product under the drug and biological pass-through process. Conversely, if the key component of the candidate pass-through product is a biological and that biological is functioning as an implantable device or the key component of the product is the implantable delivery system for the biological, then we would evaluate the product under the device pass-through process.

What are the criteria that a device must meet to be eligible for a transitional pass-through payment?

To be included in a category a device (including an implantable biological) must meet all of the following criteria:

1. If required by the FDA, the device must have received FDA approval or clearance. This requirement is met if a device 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 Title 42 of the Code of Federal Regulations or has received 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 Social Security Act. However, the application process does not result in a coverage determination. Neither assignment of a HCPCS code nor approval of a device for transitional pass-through payment

implies coverage of the device. Furthermore, each use of a qualified device is subject to medical review for determination of whether its use was reasonable and necessary in that particular case.

3. The device must —
   a. Be an integral and subordinate part of the service furnished;
   b. Be used for one patient only;
   c. Come in contact with human tissue; and
   d. Be surgically implanted or inserted whether or not the device remains with the patient when the patient is released from the hospital.
4. The device is not any of the following:
   a. Equipment, an instrument, apparatus, 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).
   b. A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker).
   c. A material that may be used to replace human skin (for example, a biological or synthetic material).

What are the criteria that CMS uses to establish a new category of devices?

1. A device to be included in a proposed new category is not appropriately described by any of the existing (either currently active or expired) categories established for transitional pass-through payments. A device for which a brand-specific application was made before December 1, 2000 that was determined to be eligible for transitional pass-through payment is not eligible to be placed in a new category. Such devices were placed in one of the initial categories that were effective April 1, 2001. A complete list of established device categories used presently or previously for pass-through payment is found on the OPPS web site, currently under *http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp.* A category of devices does not appropriately describe the new device if the applicant adequately demonstrates that the candidate device is not similar to devices (including related predicate devices) whose costs are reflected in the OPPS claims data in the most recent OPPS update. In addition, the applicant must demonstrate substantial clinical improvement, discussed below, as described in the November 10, 2005 OPPS final rule (70 FR 68630-68631).

2. A device to be included in the category was not being paid for as an outpatient service as of December 31, 1996.

3. Substantial Clinical Improvement: CMS determines that a device to be included in the category will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to all available treatments or diagnostic tests. Whether a candidate device provides substantial clinical improvement is evaluated by one or more of the following:
   a. The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
   b. The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than is currently possible and this earlier diagnosis results in better outcomes. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
   c. Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:
      - Reduced mortality rate with use of the device.
      - Reduced rate of device-related complications.

- Decreased rate of subsequent diagnostic or therapeutic interventions (e.g., due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treated because of the use of the device.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

How does CMS determine whether the cost of devices that would be included in an additional category is "not insignificant"?

CMS considers the average cost of devices that would be included in an additional category and that are being marketed at the time the category is established to be "not insignificant" if the following conditions are met:

1. The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices.
2. The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent.
3. The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.

Are there any exceptions to the "not insignificant" cost test?

The following medical devices are exempt from the "not insignificant" cost requirements if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.
(2) A device of temperature-monitored cryoablation.

How long is a new category eligible for a pass-through payment?

A new device category is eligible for a pass-through payment for at least 2 years, but not more than 3 years beginning on the date that CMS establishes the category.

Where can I find more information about past or current transitional pass-through payments for categories of medical devices?

A complete list of established device categories used presently or previously for pass-through payment is found on the OPPS web site, currently under http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp**.**

What has to be in an application for an additional transitional pass-through category for new medical devices?

To enable CMS to make an appropriate determination that the criteria for an additional category of new medical devices are met, applications for an additional device category **must** include all of the information listed below. A separate application is required for each distinct additional category that is being requested. An application that does not include all of the following information is considered incomplete and cannot be acted upon. Those requesting the establishment of an additional category of medical devices for transitional pass-through payment under the OPPS must supply the following information:

A. Proposed name or description for the additional category.
B. Trade/brand names of any known devices fitting the proposed additional category. (Applications must include the name and description of at least one marketed medical device, or device with a Category B investigational device exemption, that would be placed in the proposed additional category.)

C. A list of all **established device categories used presently or previously for pass-through payment** that describe related or similar devices. For each established device category, provide a detailed explanation as to why that category does not encompass the nominated device(s).

D. Detailed description of the clinical use(s) of each nominated device requiring an additional category.

Describe each nominated device fully:

b. What is it? Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering.
c. What does it do?
d. How is it used?
e. What makes it different from similar devices of the same type?
f. What are its clinical characteristics, e.g., is it used for diagnosis or treatment, what is its life span, what are the complications associated with its use, for what disease processes and patient populations is it used?
g. Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.

Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. HCPCS Level I is the American Medical Association's *Current Procedural Terminology* (CPT); HCPCS Level II National Codes are alpha-numeric codes that describe medical services and supplies not contained in CPT.

If a device replaces or improves upon an existing device, identify the trade/brand name of the existing device and any HCPCS Level I and/or Level II code(s) used to identify the existing device.

Identify by name and manufacturer similar devices that would also become eligible for transitional pass-through payment under the proposed additional category, insofar as this information is known to the applicant.

E. Substantial Clinical Improvement information:

Provide a full discussion of the evidence supporting the proposition that the device for which an additional category is requested meets the substantial clinical improvement criterion. This discussion must include evidence (typically, but not necessarily, in the form of published peer-reviewed clinical trials) to demonstrate that the device under consideration satisfies one or more of the measures of "substantial clinical improvement" that are listed above in this announcement.

F. Sales and Marketing:

Provide the following information for the device(s) for which an additional category is proposed:

1. Date(s) the device for which an additional category is requested was first marketed--
   a. In the United States
   b. Outside the United States
2. Date of sale of first unit of the device nominated for an additional category--
   a. In the United States
   b. Outside the United States
3. Number of device(s) nominated for an additional category that have been sold up to the date of the application.
4. Number of facilities currently using the nominated device.
5. Projected total annual utilization for both the nominated device and for the proposed device category as a whole.
6. Indicate the annual projected utilization of the nominated device in connection with each HCPCS with which it is used. For example, projected utilization in connection with CPT code A equals 300 cases using 1 device per case; utilization in connection with CPT code B

equals 1500 cases using 3 devices per case; utilization in connection with HCPCS code C equals 50 cases with 6 devices required per case.

7. For each CPT code associated with a device, estimate annual utilization by site of service, that is, for HCPCS code A, projected utilization is 40% hospital outpatient, 30% ambulatory surgical center, 10% hospital inpatient, 20 % physician office.

G. Cost:
Indicate the current cost of the device to hospitals, that is, the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the hospitals' actual cost for the nominated device.

H. FDA Approval:
1. If the device requires approval or clearance by the Food and Drug Administration (FDA), submit a copy of the FDA approval/clearance letter.
2. If the device has an investigational device exemption (IDE), submit the FDA approval letter and indicate whether it is a "Category B" IDE.
3. If the device is covered by a guidance document or is exempt from FDA approval or clearance, provide the complete citation of the guidance level regulation or exemption from approval or clearance.
4. If a new category of devices is exempt from FDA approval or clearance, or the FDA has chosen an alternate regulatory scheme (e.g., guidance documentation during a defined period of time), then the applicant should so state, along with supporting references and citations.

I. Contact Information: Name(s), address(es), e-mail address(es) and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.

J. Other information as CMS may require in order to evaluate specific requests or that the applicant believes CMS may need to evaluate the application.

Where are applications to be sent?
Mail ***five (5)*** copies of each completed application, at least one of which should be an unbound copy, to the following address:

OPPS Additional Pass-Through Category of Device
Division of Outpatient Care
Mailstop C4-05-17
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Electronic copy requirement: Send the entire application, including all attachments and appendices, via email to DevicePTapplications@cms.hhs.gov. Email versions of the application must be compatible with standard CMS software, such as Adobe Acrobat 9.0 and Microsoft Word 2007. The email copy of application does not substitute for the hard copies required. We do not accept applications by facsimile (FAX).

Questions pertaining to the pass-through payment application process may be sent via e-mail to the Division of Outpatient Care mailbox, OutpatientPPS@cms.hhs.gov or by phone to 410-786-0378.

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