

# **Processes for Establishing New Device Categories for Pass-Through Payment and New Technology APC Assignment Hospital Outpatient Prospective Payment System (OPPS)**

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# OPPS Payment Mechanisms for New Technologies

- Pass-through payment for new devices
- Pass-through payment for new drugs and non-implantable biologicals
- New Technology Ambulatory Payment Classification (APC) payments for new services
- Annual updates of standard clinical APC costs

# OPPS Pass-Through Device Category Process Overview

- Submission of applications for device pass-through for surgically inserted or implanted devices on ongoing basis
- Evaluation conducted by a clinical review team of in-house CMS physicians, coders, and policy analysts
- Team's criteria are those listed in Nov. 1, 2002 *Federal Register* (67 FR 66781), modified by November 10, 2005 *Federal Register* (70 FR 68630)
- Application requirements and criteria are discussed on OPPS web page:
  - [http://www.cms.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage)

# Evaluation of Proposed New Device Category - Criteria

- FDA approvals or clearances, if required by FDA
- Item is considered reasonable and necessary, per section 1862(a)(1)(A) of the SSA
  - Creating a code for a new device category does not mean it is reasonable and necessary for any individual use
  - Each use of a new device category is subject to medical review by Medicare contractors

# Evaluation of Proposed New Device Category – Criteria, continued

- Device must be:
  - Integral and subordinate part of service furnished
  - Used for one patient only
  - Come in contact with human tissue
  - Surgically implanted or inserted
    - Includes insertion/implantation through a natural or surgically created orifice
    - As of 1/1/10 implantable biologicals are considered devices
- Device must not be:
  - Equipment, instrument, etc., or item considered a depreciable asset
  - Material or supply furnished incident to service
  - Material used to replace human skin

# Evaluation of Proposed New Device Category – Criteria, continued

- Device is not appropriately described by any previous or current pass-through device categories
  - Complete list of device categories on the OPPS web site at [http://www.cms.gov/HospitalOutpatientPPS/Downloads/DeviceCats\\_OPPSUpdate.pdf](http://www.cms.gov/HospitalOutpatientPPS/Downloads/DeviceCats_OPPSUpdate.pdf)
- Two tests to determine if device is appropriately described by another category:
  - Must show that device is not similar to devices in the OPPS claims data in most recent OPPS update; or
  - Must demonstrate that device provides a substantial clinical improvement for Medicare beneficiaries
- Device has not been paid as part of an outpatient service as of 12/31/1996 (statutory language)

# Evaluation of Proposed New Device Category – Criteria, continued

- Device demonstrates “substantial clinical improvement” in diagnosis or treatment or improves functioning of malformed body part compared to benefits of devices in previous categories or other available treatments
- Measures of substantial clinical improvement:
  - Treatment option for a patient population unresponsive to currently available treatments
  - Offers ability to diagnose a medical condition currently undetectable or earlier than currently possible
  - Use of device significantly improves clinical outcomes

# Evaluation of Proposed New Device Category – Criteria, continued

- Examples of significantly improved clinical outcomes
  - Reduced mortality
  - Reduced rate of device-related complications
  - Decreased rate of subsequent diagnostic interventions
  - Decreased future hospitalizations
  - More rapid beneficial resolution of disease process
  - Decreased pain, bleeding, or other quantifiable symptoms
  - Reduced recovery time



# Evaluation of Proposed New Device Category – Criteria, continued

- Cost of device is “not insignificant” relative to APC payment of procedures associated with device
- Three cost significance subtests:
  - Average cost of new device exceeds 25 percent of applicable APC payment
  - Average cost of new device exceeds cost of device related portion of APC payment by at least 25 percent
  - Difference between average cost of new device and cost of device related portion of APC payment exceeds total APC payment by 10 percent
- Device related portions for each APC are on OPPS web page:  
[http://www.cms.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage)

# Implantable Biologicals as Devices

- Effective 1/1/10, surgically implanted biologicals evaluated and paid under device pass-through criteria and payment methodology
- Pertains to new biologicals not paid as or submitted for pass-through consideration prior to 1/1/10
- Policy discussed in 11/20/09 (74 FR 60471) and in 11/24/10 (75 FR 71924) *Federal Registers*

# Establishment of New Pass-Through Device Category

- If eligible, we develop HCPCS code and descriptors, and APC for new category, effective in the next available OPPS quarterly update after a determination of eligibility
- New device category eligible for pass-through payment for at least 2 but not more than 3 years
- Payment based on hospital-specific charges adjusted to cost, less the median cost of similar devices already in the APC payment (i.e., offset), if applicable

# OPPS New Technology APC Process Overview

- Application submission for a new, complete service (as defined in November 30, 2001 *Federal Register*)
- Evaluation of new service to determine appropriate New Tech APC assignment
- If determined to be a new, complete service, assignment of service to New Tech APC and dissemination of coding information if needed
- Effective in the next available OPPS quarterly update after we make a determination that a complete service is eligible

# Characteristics of New Technology APCs

- New Tech APCs consist of a series of cost bands (e.g., \$0-\$10, \$50-\$100, \$3000-\$3500, etc.)
- Services paid at mid-point of cost bands
- Assignment of service to New Tech APC based on estimated cost for the service
- Services remain in New Tech APCs until we have adequate OPPS claims data to support assignment to a clinical APC (typically two years)

# Evaluation of Proposed New Service for Assignment to New Tech APC

- Evaluation conducted by a clinical review team of in-house CMS physicians, coders, and analysts
- Team's criteria are those listed in Nov. 30, 2001 *Federal Register* (66 FR 59897)
- Application process and criteria discussed on OPPS web page:
  - [http://www.cms.gov/HospitalOutpatientPPS/04\\_passthrough\\_payment.asp#TopOfPage](http://www.cms.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage)

# Evaluation Criteria for New Technology APC Assignment

- Service represents a complete, comprehensive service
- Service cannot be appropriately described by existing HCPCS codes
- Service could not have been adequately represented in claims data used for most current annual OPPS update
- Service is not a device, drug, or biologic that is eligible for transitional pass-through payment
- Service cannot be reasonably placed into existing APC group in terms of clinical characteristics & resource cost

# Evaluation Criteria for New Technology APC Assignment, continued

- Service is under scope of Medicare benefits, per section 1832(a) of the SSA (a covered benefit)
- Service is determined to be reasonable and necessary, per section 1862(a)(1)(A) of the SSA
  - If we assign codes to services and place them into a New Tech APC, this is not considered a determination of reasonableness and necessity
  - Each use of a New Technology service is subject to medical review by Medicare contractors



# Questions on the OPPS Device Pass-Through and New Technology APC Application Processes

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