

# **The Pass-Through Payment: *Navigating the CMS Maze to Determine if Your Technology is Eligible***

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# Objectives

- Understand the importance of substantial clinical improvement and how it impacts a service's payment from CMS.
- Become familiar with the different OPPS status category payments:
  - Transitional Pass-Through payment
  - New Tech APC designation
- Know how to determine if your technology is eligible for Inpatient Add-on Payment.
- Know where the critical information (application) is posted on the CMS website.



# Status Categories to Obtain Additional Payment

1. Transitional pass-through (OPPS)
  - device
  - drug
  - radiopharmaceutical
  - biological
2. New technology APC (OPPS)
3. Inpatient add-on (IPPS)

# Substantial Clinical Improvement...

## What does this really mean?

- This term designates that a technology represents an advance that *substantially improves*, relative to technologies previously/currently available, the diagnosis or treatment of Medicare beneficiaries
- CMS makes a determination of SCI based on clinical outcomes (evidence/data)
- Decision of determination is conducted by a team of CMS medical officers, coders, and policy analysts



# Substantial Clinical Improvement the *Evaluation*

- CMS evaluates a request for special payment for a new technology against the following criteria (SCI):

***Does the device:***

1. Offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments?
2. Offer 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 allowed by currently available methods?
3. Have evidence to support its use to make a diagnosis that affects the management of the patient?



# Substantial Clinical Improvement the *Evaluation*

## ***Does the device:***

4. Significantly improve clinical outcomes for a patient population as compared to currently available treatments?
  - Reduced mortality rate with use of the device
  - Reduced rate of device-related complications
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, 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 treatment because of the use of the device
  - Decreased pain, bleeding, or other quantifiable symptom
  - Reduced recovery time



# Substantial Clinical Improvement the *Evidence*

- Applicants should submit all relevant information to demonstrate that their technology represents a substantial clinical improvement. This may include:
  - Clinical Trial Data
  - Post market data
  - Published Peer-Reviewed Articles

# Transitional Pass-Through Status

# Pass-Through Device Category the *Process*

- Application is submitted for surgically inserted or implanted device
- Evaluation is conducted for the proposed new device category
- If criteria is met, establishment of a new pass-through device category, including development of device category coding information is completed
- The final determination may be made effective in any quarter that CMS makes a determination that a new category is eligible



# Pass-Through Device Category the *Submission*

- CMS accepts applications on an ongoing basis
- Quarterly deadlines are for benchmarks
- Important to address each element completely at the time of application to facilitate review, otherwise application not considered for earliest implementation date



# The Timeline

<b>CMS must have application and all necessary paperwork by first business day in ...</b>	<b>Earliest date to be considered for pass-through status effective...</b>
March	July 1
June	October 1
September	January 1
December	April 1

# Pass-Through Device Category the *Evaluation*

- Evaluation is 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 (70 FR 68630)
- Criteria for evaluation are also discussed on OPPS web page



# Pass-Through Device Category the *Criteria*

- FDA approvals or clearances, if required by FDA
- The medical service is considered reasonable and necessary
  - If CMS assigns pass-through status to a device and gives it a code, is not automatically considered a determination of reasonableness and necessity
- Each use of a new device category is subject to medical review by Local Medicare Contractors



# Pass-Through Device Category the *Criteria*

- 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 (New as of 1/1/06)
- Device must not be:
  - Equipment, instrument, etc., considered a depreciable asset
  - Material or supply furnished incident to service
  - Material used to replace human skin



# Pass-Through Device Category the *Criteria*

- Device is not appropriately described by any existing or previously existing device categories
  - Complete list of device categories on the OPPS web site
- Device has not been paid for outpatient services as of 12/31/1996

# Pass-Through Device Category the *Criteria*

- 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



# Pass-Through Device Category the *Criteria*

- Cost of device is “not insignificant” relative to APC payment of procedures associated with device
- Three cost significance subsets:
  - 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



# What Happens Next?

- If eligible, CMS develops a “C-code”, long and short descriptors, and APC for the new category
- New device category is eligible for pass-through payment at least 2 and no more than 3 years
- Payment based on hospital-specific charges reduced to cost, less the cost of similar devices already in the APC payment (i.e., offset), if applicable





# **New Technology Ambulatory Payment Classification (APC) Designation**

# Overview

- Presently there are 20 New Tech APCs
- Payments range from \$5,250-\$9,750
- You don't apply for a New Tech APC, you apply to be placed within one

# New Tech APC the *Process*

- Application submission for a new complete service (as defined in November 30, 2001 Federal Register)
- Evaluation of proposed new service for assignment
- Assignment of service to New Tech APC, including development and dissemination of coding information
- Assignment to a New Tech APC may be made effective in any quarter that CMS makes a determination that a new service is eligible



# New Tech APC the *Submission*

- CMS accepts applications on an ongoing basis
- Quarterly deadlines are for benchmarks
- Important to address each element completely at time of application to facilitate review



# The Timeline

<b>CMS must have application and all necessary paperwork by first business day in ...</b>	<b>Earliest date to be considered for pass-through status effective...</b>
March	July 1
June	October 1
September	January 1
December	April 1

# New Tech APC the *Evaluation*

- Evaluation conducted by a clinical review team of in-house CMS physicians, coders, and policy analysts
- Team's criteria are those listed in Nov. 30, 2001 Federal Register (66 FR 59897)
- Criteria also discussed on OPPS web page

# New Technology APC

## *the Criteria*

- Service must:
  - represent a complete, comprehensive service having a ***beginning, middle, and end*** (not an adjunct)
  - not be appropriately described by existing HCPCS codes
  - not have been adequately represented in claims data used for most current annual OPPS update
  - not be a device, drug, or biologic that is eligible for transitional pass-through payment
  - not be reasonably placed into existing APC group in terms of clinical characteristics & resource costs
  - be truly new and significant enough to warrant having its own code



# New Technology APC *the Criteria*

- If CMS assigns codes to services and places 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 Local Medicare Contractors
  - assignment of payment information only indicates how service may be paid if covered



# New Technology APC

## *Establishing the Cost*

- CMS uses a variety of data to determine the cost of a procedure including:
  - cost, resources, and service detail in the application
    - (you provide the data)
  - cost information from claims data for similar services
  - other cost and resource information available for the service or similar services
- CMS determines an estimated cost of the procedure, *including the new technology items*



# What Happens Next?

- If eligible, CMS established a new HCPCS **C-code** and places the service in the appropriate New Technology APC
- Services generally remain in New Tech APCs until CMS has sufficient OPPS claims data to assign them to clinical APCs



# Inpatient Add-on Payments for New Technology



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# 3. Inpatient Add-on Payments for New Technology

- Recognizes expensive costs of new medical services and technologies that meet certain criteria and are used to treat Medicare beneficiaries
- Before establishing any add-on with respect to a new technology, CMS will seek to identify and assign one or more DRGs associated with the technology based on similar clinical or anatomical characteristics and the cost of the technology



# Inpatient New Tech Add-on the *Criteria*

- **Is it truly new?**

- technology may be considered new for 2-3 years after becoming available on the market
- the FDA approval date is usually the date that a technology would be considered to be available on the market, but not always
- new indication
- applicants may apply for new technology add-on payments several months prior to the technology receiving FDA approval as long as FDA approval is granted before CMS makes its decisions for the IPPS final rule
- after a technology is available on the market for 2-3 years, it is no longer considered “new” because cost of cases involving the technology have been absorbed into the DRG(s)
- technologies that are substantially similar to older technology considered new

# Inpatient New Tech Add-on the *Criteria*

- **Substantial Clinical Improvement**
  - Is there demonstrated substantial clinical improvement over existing technologies?
  - Do you have the evidence (data) to substantiate?
- **High Cost**
  - Is the technology inadequately paid under the DRG system as evidenced by meeting a defined cost-threshold (defined in terms of standardized charges)
  - Thresholds(standardized charges) for each DRG is published annually in Table 10 of the IPPS final rule



# Inpatient New Tech Add-on the *Process*

- CMS will meet with applicants to determine if they are eligible and to discuss the required data.
- The technology must meet a “cost threshold”
- The applicant submits data to CMS verifying that the average charge per case exceeds the DRG threshold published in Table 10 of the IPPS final rule
- If the technology is across multiple DRGs then the case-weighted average charge per case must exceed the case-weighted threshold by DRG
- Applicants can submit a sample of data demonstrating they meet the cost criteria using multiple source(s) such as:
  - **MedPAR**
  - **Clinical Trial Claims Data**
  - **External (non MedPAR) data (Premier, other non Medicare claims databases, actual claims the manufacturer collects from hospitals)**

# Inpatient New Tech Add-on the Codes

- In order to receive new technology add-on payments, the technology must be uniquely identifiable within the IPPS DRG system (i.e. have an ICD-9-CM procedure code)
- Applicants can use a combination of current ICD-9-CM codes and DRGs to uniquely identify their technology
- Applicants can apply for a new ICD-9-CM code



# Inpatient New Tech Add-on the *Payment*

- CMS makes add-on payments in the following manner
  - only individual cases that are more costly than average will receive an additional amount
  - the additional payment is capped at 50% of the additional cost of the technology
  - cases receive less add-on payment if the case costs less than DRG payment amount + 50% of the cost of the technology



# Add-on Payment *Example*

- Total Covered Charges: \$50,000
- DRG Payment: \$20,000
- Cost of Technology: \$3,000
- Maximum Add on Payment: \$1,500 (50 percent of the cost of the technology)
- Hospital Specific Operating Cost to Charge Ratio: 0.50
- Total Costs:  $\$50,000 * 0.50 = \$25,000$
- CMS pays the lesser of 50 percent of the costs of the new medical service or technology or 50 percent of the amount by which the total covered costs (as determined above) of the case exceed the DRG payment.
- Total Add on Payment: \$1,500



# Inpatient New Tech Add-on

## *Multiple Manufacturers*

- CMS makes add-on payments for all manufacturers of a technology approved for new technology add-on payments

### Actual Example

- Medtronic submitted application for its Insync® Defibrillator System, also known as Cardiac Resynchronization Therapy with Defibrillation (CRT-D)
- Application was submitted in Oct 2003 for add-on payment that would begin in FY 2005
- Technology is identified by ICD-9-CM procedure codes 00.51 (Implantation of Total CRT-D System) or 00.54 (Implantation or Replacement of Pulse Generator Device Only)
- All CRT-Ds (manufactured by Medtronic, Johnson and Johnson (Guidant) and St. Jude) are substantially similar and are identified using ICD-9-CM procedure codes 00.51 and 00.54,
- Therefore, the add-on payment for this technology was extended to all manufacturers of CRT-D



# Inpatient New Tech Add-on the *Submission*

- **There are specific deadlines for the submission of the application and the applicable data**
- Application available on CMS web site after publication of the IPPS final rule (approximately early/mid August.)
- Applicants must submit application and tracking form to CMS by the designated deadline
- Application includes several questions which help applicant to demonstrate how it meets each criterion
- CMS works with applicants who have questions about what is required
- CMS will post tracking form on IPPS new technology webpage



# What Happens Next?

- **Application Review and Approval Process**
  - Applicants are asked to present their technology at the annual CMS Town Hall Meeting in the Spring to discuss substantial clinical improvement of the technology
  - Announcement of CMS initial determination and/or concerns is made public in the IPPS proposed rule ( published in April)
  - Initial determination subject to public comments (60 day comment period after publication of proposed rule)
  - Final decision announced in final rule published in August  
(All information made public.)
  - Approvals are effective beginning with discharges on or after October 1, and continue until the technology's newness period expires



# Useful Links...

<b>Centers for Medicare and Medicaid Services homepage</b>	<a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a>
<b>OPPS Transitional Pass-Through Application-device</b>	<a href="http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf">www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf</a>
<b>IPPS New Technology Application</b>	<a href="http://www.cms.hhs.gov/AcuteInpatientPPS/Downloads/FY2009_New%20Technology%20App.pdf">www.cms.hhs.gov/AcuteInpatientPPS/Downloads/FY2009_New%20Technology%20App.pdf</a>
<b>OPPS New Technology APC Application</b>	<a href="http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/newtechapc.pdf">www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/newtechapc.pdf</a>
<b>OPPS Transitional Pass-Through Application-drugs, radiopharmaceuticals, biologics</b>	<a href="http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf">www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf</a>

