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# **Overview of the Medicare Inpatient Prospective Payment System (IPPS) & New Technology Add-on Payment Provision**

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# Inpatient Add-on Payments for New Technology

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- Section 1886 (d)(5)(K) and (L) of the Social Security Act
- 42 CFR 412.87 & 42 CFR 412.88
- Effective for discharges on or after 10/01/2001
- 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 MS-DRGs associated with the technology based on similar clinical or anatomical characteristics and the cost of the technology.

# Inpatient New Technology Criteria

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- **New**
  - ✓ Technology may be considered new for 2-3 years after becoming available on the market.
- **Substantial Clinical Improvement**
  - ✓ Demonstrated substantial clinical (diagnosis or treatment) improvement over existing technologies.
- **High Cost**
  - ✓ Technology must be inadequately paid under the MS-DRG system as evidenced by meeting a defined cost-threshold (defined in terms of standardized charges).
  - ✓ Thresholds for each MS-DRG published annually in Table 10 of the IPPS final rule.

- Newness period begins (clock starts ticking) when a technology is released onto the open market and lasts for 2 to 3 years.
- The FDA approval/clearance date is usually the date that a technology would be considered to be available on the market, but not always.
- Technologies that are substantially similar to older technologies are not considered new.

## Newness Cont.

- CMS uses the MedPAR claims database to recalibrate MS-DRG relative weights.
- There is usually a two-year lag for current claims-data to be included in the MedPAR.
- Because of this time lag, costs of cases involving a **new** technology are not fully reflected in the recalibration of the MS-DRG relative weights.
- 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 MS-DRG(s).

## Newness Cont.

- 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 by July 1 before the final IPPS rule is published.

### Example

Expected FDA approval: May 2011

- Applicant submits an application in November 2010.
- If approved for new technology add-on payments, the payments would begin October 1, 2011 (Federal Fiscal Year 2012).
- Technology would be eligible for add-on payments through Federal fiscal year 2014 (payments would cease September 30, 2014).

## Substantial Similarity (74 FR 43814)

1. Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; and
2. Whether a product is assigned to the same or a different DRG); and
3. Whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population

# Substantial Clinical Improvement

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- This criterion is intended to limit the additional payment to those new technologies that represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- Evaluation of clinical outcomes is conducted by a team of CMS medical officers, coders and policy analysts.



## Substantial Clinical Improvement Cont.

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- CMS evaluates a request for special payment for a new technology against the following criteria:
  - ⌚ The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
  - ⌚ 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 allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

## Substantial Clinical Improvement Cont.

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- 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 (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 Cont.

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- Applicants should submit all relevant information to demonstrate that their technology represents a substantial clinical improvement. This may include:
  - 💡 Clinical Trial Data
  - 💡 Published Peer-Reviewed Articles
  - 💡 Other information relevant to clinical effect of the technology

## General Information

- Applicants must meet a “cost threshold”.
- The applicant submits data to CMS verifying that the average charge per case exceeds the MS-DRG threshold published in Table 10 of the IPPS final rule.
- If technology is across multiple MS-DRGs then the case-weighted average charge per case must exceed the case-weighted threshold by MS-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.

- Charges per case must be standardized (per instructions in application).
- Applicants should provide a sample of data that is of statistical significance.
- Applicants are encouraged to collect claims data during clinical trial (UB-92).
- Multiple databases are encouraged but not necessary. CMS will work with the applicant on what the applicant needs to submit.

# Cost Cont.

## Example

MS-DRG	Cases	Case Weighted Amount	Table 10 Threshold	Table 10 Case Weighted Threshold	Stdz. Charges	Stdz. Charges Case Weighted Amount
220	20	40.0%	\$93,832	\$37,533	\$110,000	\$44,000
221	30	60.0%	\$81,272	\$48,763	\$90,000	\$54,000
<b>Total</b>	<b>50</b>	<b>100%</b>	<b>\$175,104</b>	<b>\$86,296</b>	<b>\$200,000</b>	<b>\$98,000</b>

Because the average case-weighted charge per case exceeds the case weighted MS-DRG threshold, the technology would meet the cost criterion.

# Add-on Payment

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- In order to receive new technology add-on payments, the technology must be uniquely identifiable within the IPPS MS-DRG system.
- Applicants can use a combination of current ICD-9-CM codes and/or MS-DRGs to uniquely identify their technology OR...
- Applicants can apply for a new ICD-9-CM code.

# Add-on Payment Cont.

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- CMS makes add-on payments in the following manner (see appendix for more info):
  - 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 MS-DRG payment amount + 50% of the cost of the technology



# Add-on Payment Example 1

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- Total Covered Charges: \$38,000
- MS-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:  $\$38,000 * 0.50 = \$19,000$
- 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 MS-DRG payment.
- Total Add on Payment: \$0

## Add-on Payment Example 2

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- Total Covered Charges: \$50,000
- MS-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 MS-DRG payment.
- Total Add on Payment: \$1,500

# Add-on Payment Example 3

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- Total Covered Charges: \$44,000
- MS-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:  $\$44,000 * 0.50 = \$22,000$
- 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 MS-DRG payment.
- Total Add on Payment: \$1,000

# Multiple Manufacturers

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- 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 (even those manufactured by other device companies) 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-Ds.

# Application Information

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- **Submission of Application and Data**
  - ✓ Application available on CMS web site after publication of the IPPS final rule.
  - ✓ Applicants must submit application and tracking form to CMS by the designated deadline (usually in the Fall).
  - ✓ 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.

# Timeline for Applications and Evaluation

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- **October/November**– Applications due for the upcoming federal fiscal year (Tracking forms posted online as applications received)
- **February**– TownHall Meeting to discuss Substantial Clinical Improvement
- **April**– IPPS proposed rule published
- **April through June**– Public Comment Period Open
- **August 1**– IPPS Final rule published with final decisions
- **October 1**-- Payment begins for approved technologies

# Useful Links

<b>Centers for Medicare and Medicaid Services</b>	<a href="http://www.cms.hhs.gov">http://www.cms.hhs.gov</a>
<b>CMS Inpatient Homepage</b>	<a href="http://www.cms.hhs.gov/AcuteInpatientPPS/">http://www.cms.hhs.gov/AcuteInpatientPPS/</a>
<b>IPPS New Technology Homepage</b>	<a href="http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp">http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp</a>
<b>CMS Coverage Homepage</b>	<a href="http://www.cms.hhs.gov/CoverageGenInfo/">http://www.cms.hhs.gov/CoverageGenInfo/</a>
<b>IPPS Federal Register Notices</b>	<a href="http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp">http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp</a>
<b>Council on Technology and Innovation</b>	<a href="http://www.cms.hhs.gov/CouncilonTechInnov/">http://www.cms.hhs.gov/CouncilonTechInnov/</a>

# CMS New Technology Contacts

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- IPPS New Technology:  
Tiffany Swygert; Michael Treitel
- ICD-9-CM Coding  
Pat Brooks
- OPPS Pass-through (Devices) :  
Barry Levi
- New Technology APC:  
Barry Levi
- OPPS pass-through (Drugs & Biologicals):  
Majorie Baldo