



News Flash - The revised Acute Inpatient Prospective Payment System Fact Sheet (November 2007), which provides general information about the Acute Inpatient Prospective Payment System (IPPS) and how IPPS rates are set, is now available in print format. To place your order, visit http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html scroll down to "Related Links Inside CMS" and select "MLN Product Ordering Page."

MLN Matters Number: MM5860 Related Change Request (CR) #: 5860

Related CR Release Date: May 16, 2008 Effective Date: October 1, 2008

Related CR Transmittal #: R1509CP Implementation Date: October 6, 2008

Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit

Note: This article was updated on July 6, 2013, to reflect current Web addresses. This article was previously revised on May 19, 2008, to show that the Transmittal 1498 for this Change Request was replace with Transmittal 1509 on May 16, 2008. The web address for the transmittal was also changed. All other information remains the same.

Provider Types Affected

Providers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), and/or Part A/B Medicare Administrative Contractors (A/B MACs)) for services provided to Medicare beneficiaries relating to replaced medical devices

Provider Action Needed



This article is based on Change Request (CR) 5860 which provides instructions for billing replaced devices that are received without cost or with a credit. It also includes Medicare contractor instructions for how to reduce the IPPS payment based on the amount of the credit received by the hospital for the replaced device.

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CR 5860 instructs that Medicare is not responsible for the full cost of a replaced device if a hospital receives a partial or full credit, either due to a recall or service during the warranty period. Therefore, when a hospital receives a credit for a replaced device that is 50% or greater than the cost of the device, hospitals are required to bill the amount of the credit in the amount portion for value code FD.



See the Background and Additional Information Sections of this article for further details regarding these changes.

Background

In recent years, there have been several field actions and recalls with regard to failure of implantable cardiac defibrillators (ICDs) and pacemakers. In many of these cases, the manufacturers have offered replacement devices without cost to the hospital or offered credit for the device being replaced if the patient required a more expensive device. In some circumstances, manufacturers have also offered, through a warranty package, to pay specified amounts for un-reimbursed expenses to persons who had replacement devices implanted.

The Centers for Medicare & Medicaid Services (CMS) believes that incidental device failures that are covered by manufacturer warranties occur routinely. Though device malfunctions may be inevitable as medical technology grows increasingly sophisticated, CMS believes that early recognition of problems would reduce the number of people who would be potentially adversely affected by these device problems.

In addition to concerns for overall public health, CMS also has a fiduciary responsibility to the Medicare Trust Fund to ensure that Medicare pays only for covered services. Therefore, CMS believes it is appropriate to reduce the Medicare payment in cases in which an implanted device is replaced:

- At reduced or no cost to the hospital; or
- With partial or full credit for the removed device.

To address the issue, CMS issued CR 4058 (Transmittal 741, November 4, 2005, which can be found at http://www.cms.gov/Regulations-and-Guidance/Transmittals/downloads/R741CP.pdf on the CMS website, and you can find its corresponding MLN article at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM4058.pdf on the CMS website. CR

MLN/MLNMattersArticles/Downloads/MM4058.pdf on the CMS website. CR 4058 provided instructions for billing and processing claims with the following

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condition codes 49 and 50 which allow CMS to identify and track claims billed for replacement devices.

| Condition Code | Title | Description |
|-------------------|---|--|
| 49 | Product Replacement within Product Lifecycle | Replacement of a product earlier than the anticipated lifecycle due to an indication that the product is not functioning properly. |
| 50 | Product Replacement for Known Recall of a Product | Manufacturer or FDA has identified the product for recall and therefore replacement. |

Medicare is not responsible for the full cost of the replaced device if the hospital is receiving a partial or full credit, either due to a recall or due to service during the warranty period.

Therefore, hospitals are required to bill the amount of the credit in the amount portion for value code FD when the hospital receives a credit for a replaced device that is 50% or greater than the cost of the device.

Beginning with discharges on or after October 1, 2008, Medicare will reduce the hospital reimbursement, for one of the applicable Medicare Severity Diagnosis Related Groups (MS-DRGs) listed in the table below, by the full or partial credit a provider received for a replaced device. This adjustment is consistent with the Social Security Act (Section 1862(a)(2)), which excludes from Medicare coverage an item or service for which neither the beneficiary, nor anyone on his or her behalf, has an obligation to pay. Section 1862 (a)(2) of the Social Security Act can be found at http://www.ssa.gov/OP_Home/ssact/title18/1862.htm on the Internet.

For discharges on or after October 1, 2008:

- Hospitals must use the combination of condition code 49 or 50, along with value code FD to correctly bill for a replacement device that was provided with a credit or no cost. The condition code 49 or 50 will identify a replacement device while value code FD will communicate to Medicare the amount of the credit, or cost reduction, received by the hospital for the replaced device.
- Medicare will deduct the partial/full credit amount, reported in the amount for value code FD from the final IPPS reimbursement when the assigned MS-DRG is one of the MS-DRGs applied to this policy.

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| Diagnostic Related Groups (DRGs) Subject to Final Policy | | | |
|--|--------------------|---|--|
| Major Diagnostic Category (MDC) | MS-DRG | Narrative Description of DRG | |
| PRE | 1 & 2 | Heart Transplant or Implant of Heart Assist System with and without MCC, respectively (former CMS-DRG 103, Heart Transplant or Implant of Heart Assist System) | |
| 1 | 25 & 26 | Craniotomy and Endovascular Intracranial Procedure with MCC or with CC, respectively (former CMS-DRG 1, Craniotomy Age > 17 With CC) | |
| 1 | 26 & 27 | Craniotomy and Endovascular Intracranial Procedure with CC or without CC/MCC, respectively (former CMS-DRGs 2, Craniotomy Age > 17 Without CC) | |
| 1 | 40 & 41 | Peripheral & Cranial Nerve & Other Nervous System Procedure with MCC; or with CC or Peripheral Neurostimulator, respectively (former CMS-DRG, 7 Peripheral & Cranial Nerve & Other Nervous System Procedures With CC) | |
| 1 | 42 | Peripheral & Cranial Nerve & Other Nervous System Procedure without CC/MCC (former CMS-DRG 8, Peripheral & Cranial Nerve & Other Nervous System Procedures without CC) | |
| 1 | 23 & 24 | Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant; and without MCC [or Chemotherapy Implant], respectively (former CMS-DRG 543, Craniotomy With Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis) | |
| 3 | 129 & 130 | Major Head & Neck Procedures with CC/MCC or Major Device; or without CC/MCC, respectively (former CMS-DRG 49, Major Head & Neck Procedures) | |
| 5 | 216, 217, & 218 | Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheterization With MCC; or with CC; or without CC/MCC, respectively (former CMS-DRG 104, Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization) | |
| 5 | 219, 220, & 221 | Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC; or with CC, or without CC/MCC, respectively (former CMS-DRG 105, Cardiac Valve & Other Major Cardiothoracic Procedures Without Cardiac Catheterization) | |
| 5 | 237 | Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm Repair (former CMS-DRG 110, Major Cardiovascular Procedures With CC) | |
| 5 | 238 | Major Cardiovascular Procedures without MCC (former CMS-DRG 111, Major Cardiovascular Procedures without CC) | |
| 5 | 260, 261, & 262 | Cardiac Pacemaker Revision Except Device Replacement with MCC, or with CC, or without CC/MCC, respectively (former CMS-DRGs117, Cardiac Pacemaker Revision Except Device Replacement) | |
| 5 | 258 & 259 | Cardiac Pacemaker Device Replacement With MCC, and Without MCC, respectively (former CMS-DRG 118, Cardiac Pacemaker Device Replacement) | |
| 5 | 226 & 227 | Cardiac Defibrillator Implant without Cardiac Catheterization with MCC and without MCC, respectively (former CMS-DRG 515, Cardiac Defibrillator Implant without Cardiac Catheterization) | |

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|--|--------------------|--|--|--|
| Major Diagnostic Category (MDC) | MS-DRG | Narrative Description of DRG | | |
| 5 | 215 | Other Heart Assist System Implant (former CMS-DRG 525, Other Heart Assist System Implant) | | |
| 5 | 222 & 223 | Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRGs 535, Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction/Heart Failure/Shock) | | |
| 5 | 224 & 225 | Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock with MCC and without MCC, respectively (former CMS-DRG 536, Cardiac Defibrillator Implant with Cardiac Catheterization without Acute Myocardial Infarction/Heart Failure/Shock) | | |
| 5 | 242, 243, & 244 | Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (MS-DRG 551, Permanent Cardiac Pacemaker Implant with Major Cardiovascular Diagnosis or AICD Lead or Generator | | |
| 5 | 242, 243, & 244 | Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively (former CMS-DRG 552, Other Permanent Cardiac Pacemaker Implant without Major Cardiovascular Diagnosis) | | |
| 5 | 245 | AICD Lead and Generator Procedures (this is a new MS-DRG, created from AICD and generator codes moved out of CMS DRG 551) | | |
| 8 | 461 & 462 | Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC, or without MCC, respectively (former CMS-DRG 471, Bilateral or Multiple Major Joint Procedures of Lower Extremity) | | |
| 8 | 469 & 470 | Major Joint Replacement or Reattachment of Lower Extremity with MCC or without MCC, respectively (former CMS-DRG 544, Major Joint Replacement or Reattachment of Lower Extremity) | | |
| 8 | 466, 467, & 468 | Revision of Hip or Knee Replacement with MCC, with CC, or without CC/MCC, respectively (former CMS-DRG 545, Revision of Hip or Knee Replacement) | | |

Note: MDC 1 (Diseases and Disorders of the Nervous System); MDC 3 (Ear, Nose, Mouth and Throat); MDC 5 (Circulatory System); MDC 8 (Musculoskeletal and Connective Tissue)

Additional Information

The official instruction, CR 5860, issued to your Medicare FI or A/B MAC regarding this change may be viewed at http://www.cms.gov/Regulations-and-

Guidance/Guidance/Transmittals/downloads/R1509CP.pdf on the CMS website.

If you have any questions, please contact your Medicare FI or A/B MAC at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.

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