Updated January 2014

Medicare Reporting Requirements For Full or Partial Credits of Devices and Leads:  Changes for 2014

Background

Medicare

In 2007, Medicare established a policy to reduce the payment for outpatient services by the estimated portion of the APC payment attributed to device costs (device offset amount) when the hospital received a device at no cost or with full credits. Hospitals report no cost/full credit of devices by appending the “FB” modifier to the procedure code. In 2008, Medicare expanded this payment adjustment policy to include cases in which hospitals received partial credit of 50 percent or more of the cost of the replacement device. This partial credit is reported by appending the “FC” modifier to the procedure code.

Medicare’s policy has been to reduce the outpatient payment by 100 percent of the device offset amount when a hospital receives a device without cost or with a full credit. Hospital outpatient payment is reduced by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the device. Effective January 1, 2014, hospitals will report the amount of the credit received in the amount box for value code “FD” (Credit Received from the manufacturer for a Replaced Medical Device) on the claim form. Medicare will reduce the outpatient payment by the amount of the full or partial credit a hospital receives for a replaced device. The payment reduction will be limited however to the total amount of the device offset. Hospitals will no longer be required to append the “FB” or “FC” modifier when receiving a device at no cost or with a full or partial credit.

Example 1: The hospital receives a device credit of $16,500 for an ICD replacement procedure (APC 107). The device offset amount for APC 107 is $20,244. The hospital’s APC payment is reduced by $16,500.

Example 2: The hospital receives a device credit of $22,000 for an ICD replacement procedure (APC 107). The device offset amount for APC 107 is $20,244. The hospital’s APC payment is reduced by $20,244.
Private Payers
Private payers establish their own policies regarding device replacements. Providers are encouraged to gain preauthorization, when appropriate, and to fully understand payment rates before performing any replacement services.

Documentation and Medical Necessity for Device Replacements
When submitting reimbursement claims:
- Providers should provide clear, succinct documentation that reflects the reasons for the services and procedures performed.
- Physicians should clearly document the medical justification for the services provided. The absence of documented medical necessity may lead to a delayed or denied payment.
Definitions of Codes Used to Bill for Replacement Devices Offered Without Cost or with a Partial Credit

Procedure Codes
All procedure codes (CPT® and ICD-9-CM Vol. III Procedure Codes) that are normally used for lead and device replacements are appropriate to use for replacements due to a recall.

Condition Codes
Providers who bill fiscal intermediaries (FI)/MAC should use Condition Code 49 or 50. Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full or partial credit replacement device when conditions of warranty or recall are met.

- **Condition Code 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.

- **Condition Code 50:** Product Replacement for Known Recall of a Product—Manufacturer or FDA has identified the product for recall, and therefore replacement.

Value Code
Hospitals are required to report the amount of the credit in the amount portion for Value Code FD (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

Diagnosis Code
Use ICD-9-CM diagnosis codes, which specifically address cardiac devices, when appropriate:
- 996.0 Mechanical complication of cardiac device, implant, and graft
- 996.01 due to cardiac pacemaker (electrode)
- 996.04 due to automatic implantable cardiac defibrillator

C-Codes
C-Codes should be billed with all recalled devices.

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Outpatient Setting

In the outpatient setting, beginning January 1, 2014, hospitals would no longer be required to append the “FB” or “FC” modifier to the procedure code when receiving a device at no cost or with a full or partial credit. Hospitals must now report the amount of the credit received in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

Scenario 1: Device or lead is replaced without cost to the hospital
1. Enter value Code “FD” (Credit Received from the Manufacturer for a Replaced Medical Device)
2. Report the amount of the credit in the value code amount column next to value code “FD”

Scenario 2: Hospital receives full credit for replaced device or lead, but credit does not cover entire cost of new device (e.g., upgrade)
1. Enter value code “FD” (Credit Received from the Manufacturer for a Replaced Medical Device)
2. Report the difference between the usual charge for the device being implanted and the usual charge for the device for which credit was received. The charge should appear in the value code amount field.

Scenario 3: Hospital receives partial credit for replaced device or lead of 50%-99% of the cost of the new replacement device.
1. Enter value Code “FD” (Credit Received from the Manufacturer for a Replaced Medical Device)
2. Report the amount of the credit in the value code amount field

Scenario 4: Hospital receives partial credit for replaced device or lead which is less than 50% of the cost of the new replacement device or lead.
1. No reporting of credit is necessary
2. Report the cost as usual.

Inpatient Setting

To correctly bill for a replacement device that was provided with a credit of 50% or greater or no cost, hospitals must use the combination of condition code 49 or 50, along with the value code FD. Medicare will deduct the partial/full credit amount, reported in the amount for Value Code FD from the final IPPS reimbursement.

– Condition Codes 49 or 50 will identify the reason for the device replacement.
– Value Code FD will indicate to Medicare the credit or cost reduction received by the hospital for the replaced device or lead.

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Device Follow-Ups for Recalled Devices

ICDs and CRT-Ds
Currently, CMS has no national guidelines regarding the number of times a patient can have an ICD or CRT-D device checked within a calendar year. Some local coverage determinations may exist, so providers should check their local payer guidelines. Physicians establish device follow-up schedules based on individual patient need. Devices may be followed in person or remotely.

Pacemakers
Pacemaker follow-ups are covered under a national coverage determination by CMS. The guidelines for in clinic pacemaker follow-up services are:

- Single-chamber pacemakers — Twice in the first 6 months following the implant, then once every 12 months.
- Dual-chamber pacemakers — Twice in the first 6 months, then once every 6 months.

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