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## Replacement of Devices Under Warranty or Under Advisory

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### Coverage and Payment for Device Replacements Under Warranty or Under Advisory

Most payers, both private and public, have systems in place to reimburse providers for medical device replacements—both when the device is under warranty and when the device is recalled.

#### *Centers for Medicare and Medicaid Services (CMS)*

Medicare policy indicates that the amount of the Medicare payment may be reduced when a hospital receives a credit towards a replacement device. In the inpatient and outpatient settings, the credit given for the device must be equal to 50 percent or more of the total cost of the device for a payment reduction to occur.<sup>1</sup>

#### *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.

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<sup>1</sup>Centers for Medicare and Medicaid Services. Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates. P. 476-487; <http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1533-FC.pdf>. Accessed September 1, 2009.

## Codes for Replaced Devices Offered Without Cost or with a Credit

### Modifiers

In the outpatient hospital setting, the –FB or –FC modifier should be appended to the procedure code, not the device code.

#### Definition

–FB: Item provided without cost to provider, supplier, or practitioner (examples, but not limited to: covered under warranty, replaced due to defect, free samples)

–FC: Partial credit received for replaced device

### Procedure Codes

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

### Condition Code

Providers who bill fiscal intermediaries (FI)/MAC should use Condition Code 49 or 50:

*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<sup>2</sup>

*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

Providers who bill fiscal intermediaries (FI)/MAC should use Value Code FD to indicate the amount of the credit or cost reduction received by the hospital for the replaced 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<sup>3</sup>

### C-Codes

C-Codes should be billed with all recalled devices.

## Outpatient Setting

In the **outpatient setting**, when a hospital receives a replacement device without cost or receives a credit from the manufacturer, the hospital must use a combination of Condition Code

<sup>2</sup> Medicare Claims Processing Manual, Chapter 32: Billing Requirement for Special Services; <http://www.cms.hhs.gov/manuals/downloads/clm104c32.pdf>. Accessed September 1, 2009.

<sup>3</sup> Ingenix. Updatable 2009 ICD-9-CM Expert for Hospitals, Volumes 1, 2 and 3. 6th Revision. Salt Lake City, UT: 2008

49 or 50 as well as append the appropriate modifier (–FB, –FC) to the procedure code that reports the services provided to replace the device.<sup>4</sup>

**Scenario 1:** *Device is replaced without cost to the hospital*

1. Append the –FB modifier to the procedure code.
2. Report a token device charge of less than \$1.01 in the covered charges field, if required.

**Scenario 2:** *Hospital receives full credit for replaced device, but credit does not cover entire cost of new device (e.g., upgrade)*

1. Append the –FB modifier to the procedure code.
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 in the covered charges field.

**Scenario 3:** *Hospital receives partial credit for replaced device of 50% or more of the cost of the new replacement device.*

1. Append the –FC modifier to the procedure code.
2. Report the amount of the credit in the covered charges field

**Scenario 4:** *Hospital receives partial credit for replaced device less than 50% of the cost of the new replacement device.*

1. No modifier is used
2. Report the cost of device as usual.

## Inpatient Setting

In the **inpatient setting**, 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. Medicare will deduct the partial/full credit amount, reported in the amount for Value Code FD from the final IPPS reimbursement.<sup>5</sup>

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

<sup>4</sup> Medicare Claims Processing Manual, Chapter 4: Part B Hospital (Including Inpatient Hospital Part B and OPSS); <http://www.cms.hhs.gov/manuals/downloads/clm104c04.pdf>. Accessed September 1, 2009.

<sup>5</sup> Medicare Claims Processing Manual, Chapter 3: Inpatient Hospital Billing; <http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf>. Accessed September 1, 2009.



## 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. Boston Scientific recommends device checkups at least four times per year, but physicians establish device follow-up schedules based on each patient's needs. Devices may also be followed 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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