Medicare Billing for Cardiac Device Credits

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What’s Changed?

- When a hospital gets a replaced device credit 50% or greater than the device’s cost, report the amount in the claim’s FD code value portion.
- Beginning in 2020, Medicare applies a device offset cap to the Ambulatory Payment Classification (APC) claims that require implantable devices and have significant device offset (greater than 30%) based on the FD value code’s listed credit amount.

You’ll find substantive content updates in dark red font.
**Introduction**

In recent years, manufacturers recalled several Implantable Cardiac Defibrillators (ICDs) and pacemakers. The manufacturers often offered replacement devices without hospital cost or replacement device credit if the patient needed a more expensive device. In some cases, manufacturers paid unreimbursed expenses for patients who needed replacement devices implanted through a warranty package.

Learn how to bill Medicare inpatient and outpatient cardiac devices and reduce overpayments. CMS reduces hospital payments when a patient gets a reduced or no cost implanted cardiac device or partial or full credit for the removed device. The reduced payment is consistent with SSA Section 1862(a)(2). It excludes Medicare coverage for an item or service the patient, or anyone on their behalf, must pay.

Hospitals getting cardiac devices at no cost or with credit must use correct modifiers and condition codes when submitting inpatient or outpatient claims so we only pay the reasonable cost of the device and don’t make overpayments.

**Quick Start**

This table outlines key billing information for a provided or replaced manufacturer or supplier cardiac device at reduced or no cost.

### Cardiac Device Replacement Hospital Coding & Billing Requirements

<table>
<thead>
<tr>
<th>Coding or Billing Issue</th>
<th>Inpatient</th>
<th>Outpatient</th>
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<tr>
<td>What Condition Code do I use?</td>
<td>49—replaced within lifecycle 50—recalled and replaced</td>
<td>49—replaced within lifecycle 50—recalled and replaced</td>
</tr>
<tr>
<td>What Value Code and amount do I use?</td>
<td>FD—dollar amount of the price reduction or credit</td>
<td>FD—dollar amount of the price reduction or credit</td>
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<tr>
<td>How do I report a no-cost item charge?</td>
<td>N/A</td>
<td>If your system allows it, use $0.00. If $0.00 isn't allowed, use $1.00.</td>
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Basis for Reducing Cardiac Device Payments

Hospitals must report a patient’s replaced implanted device. If a hospital gets a full or partial credit from the manufacturer for a covered cardiac device under warranty, or 1 replaced because of defect or recall, they must identify and track the replacement device claims billed.

Get more information on payment adjustments for certain replaced devices at 42 CFR Section 412.89.

We reduce hospital payments when a patient gets a cardiac replacement device:

- At a reduced cost
- At no cost
- With a credit 50% or greater than the device’s cost

Charging for Recalled Devices Reminder:
The Provider Reimbursement Manual, Part 1, Section 2202.4 states, “Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.” Medical device hospital charges must reasonably relate to the medical device’s cost. When a hospital gets a replacement medical device credit, the hospital must appropriately reduce Medicare’s charges.

Coding & Billing

Under the Hospital Inpatient Prospective Payment System (IPPS), CMS pays inpatient hospital costs at predetermined patient discharge rates based on Diagnosis-Related Group (DRG) and severity level. Under the Hospital Outpatient Prospective Payment System (OPPS), CMS pays outpatient hospital costs on a rate-per-service basis that varies according to the assigned Ambulatory Payment Classification (APC).

Inpatient Billing Instructions

Get more information on inpatient billing instructions at Medicare Claims Processing Manual, Chapter 3, Section 100.8.
For under-warranty or defective items, physicians and outpatient hospitals should bill the modifiers. They describe provided items without cost to a provider, supplier, or practitioner:

**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

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

For discharges:

- Use the combination of condition code 49 or 50 and the **value code FD** (Credit Received from the Manufacturer for a Medical Device) to correctly bill a replacement device provided with a credit or no cost. The condition code 49 or 50 identifies a replacement device, and the value code FD communicates the amount of the credit or the replaced device cost reduction.

- We deduct the partial or full credit amount reported in the value code FD from the final IPPS reimbursement when the appropriate Medicare Severity Diagnosis Related Group (MS-DRG) is 1 of the MS-DRGs applied to the policy.

The **outpatient payment policy** requires reporting value code FD for medical devices provided without cost to the hospital or when the hospital gets a full or partial device credit.

**Policy Guidance**

Find more information about this policy at [Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices](#).

Since 2020, we apply a device offset cap to the APC claims that require implantable devices and have significant device offset (greater than 30%) based on the credit amount listed in the FD value code.

Condition code 53 helps identify and track medical devices provided by a manufacturer at no cost or with full credit to the hospital for a clinical trial or a free sample. When value code FD is on the claim, you must report condition code 53:

**Code 53: Initial placement of a medical device provided as part of a clinical trial or free sample**

When a hospital provides a no-cost device, (these include, but aren’t limited to, devices replaced under warranty due to recall or defect in a previous device; devices provided in a clinical trial; or devices provided as samples) the hospital charge should equal $0.00. Some hospitals’ billing systems require reporting a charge for separately billable codes for claims submitted for payment, even no-cost items.

Hospitals that implant a device provided under the OPPS with no cost to the hospital should report a charge of $0.00 for the device unless the hospital’s billing system requires an entered charge. If the hospital must submit a token charge (for example, $1.00), put it on the line with the device code.
● **42 CFR Section 419.45(b)(1)** states, when a patient gets an implanted device replaced without cost to the provider or the patient, or when the **provider gets full credit** for the cost of a replaced device, calculate the APC payment reduction by reducing the payment amount by the lesser of the amount of the credit or the device offset amount normally applied if the procedure assigned to the APC had transitional pass-through status under **42 CFR Section 419.66**.

● **42 CFR Section 419.45(b)(2)** states, in situations when the **provider gets partial credit** for the cost of a replaced device, but only when the device credit amount is greater than or equal to 50% of the cost of the replacement device, calculate the reduced payment amount by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under **42 CFR Section 419.66**.

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**Resources**

- Hospitals Did Not Comply with Medicare Requirements for Reporting Certain Cardiac Device Credits
- Medicare Claims Processing Manual, Chapter 4, Section 61.3.1–61.3.2
- Replaced Devices Offered Without Cost or With a Credit

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