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FACT SHEET
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Cardiac Device Credits: Medicare Billing

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What's Changed?

Note: No substantive content updates.

Implantable cardiac defibrillators include defibrillators, pacemakers, and their associated electrical leads. Practitioners implant these devices during either an inpatient or outpatient procedure.

Occasionally, suppliers may need to replace devices because of defects, recalls, battery depletions, or mechanical complications, which may be covered under the device manufacturer's warranty.

In recent years, manufacturers offered replacement devices without hospital cost or with replacement device credit if the Medicare patient needed a more expensive device. In some cases, manufacturers paid unreimbursed expenses for patients who needed replacement devices implanted through a warranty package.

We reduce hospital payments when a patient gets a reduced or no-cost implanted cardiac device or partial or full credit for the removed device. We don't cover items or services the patient, or anyone on their behalf, must pay.

Reducing Cardiac Device Payments

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

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

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

Charging for Recalled Devices

Section 2202.4 of the Provider Reimbursement Manual, Part 1 states, "Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient." Hospital medical device charges must reasonably relate to the medical device's cost.

Coding & Billing Requirements

Hospitals getting cardiac devices at no cost or with credit must use the correct value code and condition codes when submitting inpatient or outpatient claims so Medicare only pays the device's reasonable cost and doesn't make overpayments.

Device manufacturers sometimes issue hospital-reportable credits for recalled or prematurely failed cardiac medical devices, but they don't adjust the claims with proper condition and value codes to reduce payments, as required.

Table 1. Key Billing Information

Coding or Billing Issue	Inpatient	Outpatient
What **condition code** do I use?	**49**—Replaced within lifecycle **50**—Recalled and replaced	**49**—Replaced within lifecycle **50**—Recalled and replaced **53**—Initially placed in clinical trial
What **value code** and amount do I use?	**FD**—Dollar amount of price reduction or credit Report on the claim the replaced device credit amount in the amount section for value code FD when the hospital gets a credit 50% or greater than the device's cost.	**FD**—Dollar amount of price reduction or credit Report on the claim the replaced device credit amount in the amount section for value code FD when the hospital gets a credit 50% or greater than the device's cost.
How do I report a no-cost item charge?	N/A	If your system allows it, use **$0.00**. If $0.00 isn't allowed, use **$1.00**.

Table 2. Prospective Payment System Payments

Prospective Payment System	What we pay for...
Hospital Inpatient Prospective Payment System (IPPS)	Inpatient hospital costs at predetermined patient discharge rates based on Medicare Severity Diagnosis-Related Group (MS-DRG) and severity level
Hospital Outpatient Prospective Payment System (OPPS)	Outpatient hospital costs on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC)

For under-warranty or defective items, physicians and outpatient hospitals should bill using modifiers, which describe items provided without cost to a provider, supplier, or practitioner:

Code 49: Product Replacement within Product Lifecycle — Product replacement earlier than anticipated lifecycle due to indication the product isn't functioning properly

Code 50: Product Replacement for Known Recall — Manufacturer or FDA identified the product for recall and, therefore, replacement

For Discharges:

- Use a combination of **condition code 49 or 50** and **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. Condition codes 49 or 50 identify a replacement device, and value code FD communicates the credit amount or the replaced device cost reduction.
- We deduct the partial or full credit amount reported in the value code FD from the final IPPS payment when you use an appropriate MS-DRG from this policy.

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

We apply a cap to the FD value code on APC claims that's based on the device offset amount for procedures that require insertable or implantable devices and have significant device offset percentages (greater than 30%).

Policy Guidance

The CY 2024 Hospital OPPS final rule has more information about this policy.

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 condition code 53 is on the claim, you must report value code FD:

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

When a hospital provides a no-cost device (for example, 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 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 $0.00 device charge unless the hospital's billing system requires an entered charge. If the hospital must submit a charge (for example, $1.00), put it on the line with the device code.

- 42 CFR 419.45(b)(1) states, when the **provider gets full credit** for a replaced device's cost, calculate the APC payment reduction by reducing the payment amount by the lesser of the credit amount or the device offset amount normally applied if the procedure assigned to the APC had transitional pass-through status under 42 CFR 419.66
- 42 CFR 419.45(b)(2) states, when the **provider gets partial credit** for the replaced device's cost, but only when the device credit amount is greater than or equal to 50% of the replacement device's cost, calculate the APC payment reduction by reducing the payment amount by the lesser of the credit amount or the device offset amount normally applied if the procedure assigned to the APC had transitional pass-through status under 42 CFR 419.66

Section 100.8 of the Medicare Claims Processing Manual, Chapter 3 has more information on inpatient billing instructions.

Resources

- Hospitals Did Not Comply with Medicare Requirements for Reporting Cardiac Device Credits
- Sections 61.3.1–61.3.2 of the Medicare Claims Processing Manual, Chapter 4

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