Medtronic

Coding corner

Properly reporting a device credit for a replacement device received from a manufacturer

Background

Implanted medical devices may require early replacement for a variety of reasons (e.g., defects, recalls, mechanical complications). Manufacturers can give credits to hospitals for medical devices that must be replaced because of a recall or malfunction. The Centers for Medicare and Medicaid Services (CMS) requires hospitals to pass these manufacturer credits on to Medicare when a hospital receives a replacement device from a manufacturer that is without cost or with a credit of 50% or more of the cost of the new replacement device due to a warranty, recall or field action. Failure to pass on medical device credits results in overpayments by Medicare to hospitals. Commercial payers establish their own policies regarding reporting of manufacturer device credits.

Executive Summary

- Medicare uses information provided by hospitals and ASCs on claims[1] to appropriately reduce payments when a device credit from a manufacturer was received
- The policy applies only to specified MS-DRGs in the inpatient setting, to certain devices in the outpatient setting, and to certain procedures in the ASC setting. Device intensive procedures are generally subject to the policy (e.g., pacemaker, ICD, & VAD implants.)
- The policy only applies when the device is furnished at no cost or amount of the credit that was received for the replaced device is 50% or more of the cost of the new device.

Inpatient & outpatient hospital reporting

Report value code "FD" along with the device credit amount on the claim. If the device is furnished at no cost, report a charge of $0.00 for the device or, if the hospitals' billing system requires that a charge be entered, should submit a token charge (e.g., $1.00) to ensure proper claims adjudication.[2]

FD: Credit received from the manufacturer for a replaced medical device

Also report the applicable condition code:

50: Product replacement for known recall of a product

Manufacturer or FDA has identified the product for recall and therefore replacement

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

Ambulatory surgery center (ASC) and outpatient reporting

Use one of the following modifiers on the procedure code reported that was associated with use of the device.

FB: When device was replaced without cost or a full credit was received

FC: When partial credit of 50% or more was received

Payment implications

Inpatient: Medicare deducts the total amount of the full or partial credit – reported in the amount for value code FD – from the final MS-DRG

Outpatient: Payment reduction for claims is limited to the lesser of either 1) the device credit amount, or 2) the device offset amount specified by Medicare for the Ambulatory Payment Classification to which the procedure is assigned

ASC: A specified reduced payment amount is made in the ASC setting with the presence of either the -FC or -FB modifier based on an annual published fee schedule specific to the device credit scenario.

Lists of MS-DRGs (inpatient), devices (outpatient), and procedures (ASC) subject to the policy

Inpatient: See CMS Pub 100-20 One Time Notification Transmittal 1494 Change Request 9121 (starting on page 9)[3]

Outpatient: See published Addendum P of each annual Outpatient Prospective Payment System (OPPS) Final Rule[4]

ASC: See annual ASC FB/FC Device Adjustment Policy Files[5]

Unreimbursed medical (URM) expenses for patients

Manufacturers sometimes offer patients reimbursement up to a specified amount for payments they incur that are associated with replacement of the device (e.g., copays, deductibles). In this instance, patients typically apply to the manufacturer directly for reasonably incurred expenses as the result of their replacement.

Questions related to URM or specific patient issues for any recalled Medtronic products should be referred directly to Medtronic Patient Services at 800-551-5544 x41835 (Monday-Friday, 8am-5pm Central Time).

Contact

Cardiac Rhythm and Heart Failure, Cardiac Catheter Ablation, and Cardiac Diagnostic coding, coverage, and reimbursement information is available at medtronic.com/CRHFreimbursement.

For questions or more information, please contact Reimbursement Customer Support at 1-866- 877-4102 (M-F, 8:00 a.m. to 5:00 p.m. CT) or rs.healthcareeconomics@medtronic.com.

References

[1] Medicare Claims Processing Manual Chapter 4, section 61.3 for outpatient instructions; Chapter 3, section 100.8 for inpatient instructions; and Chapter 14, section 40.8 for ASC instructions. [online.] Available at: https://www.cms.gov/regulations-and- guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912 Accessed 8 December 2020

[2] There are additional situations for which providers may bill for no cost devices that are not described in this document. In situations where the initial device implant provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample, providers should use condition code 53. See CMS claims processing manual Chapter 32, §67.2.1 for more details on billing for no cost items due to recall, replacement, or free sample. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf

[3] CMS Pub 100-20 One Time Notification Transmittal 1494 Change Request 9121.2015 | cms.gov. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1494OTN.pdf Accessed 8 December 2020

[4] The OPPS 2024 National payment rates based on information published in the OPPS/ASC final rule CMS-1786-FC and corresponding Addendum B table which was released on November 2, 2023.
Hospital Outpatient Regulations and Notices. cms.gov. https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc Accessed November 21, 2023.
Hospital specific rates will vary based on various hospital-specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

[5] The Ambulatory Surgical Center (ASC) ASC 2024 National payment rates based on information published in the OPPS/ASC final rule CMS-1786-FC, Addendum AA table which was released on November 2, 2023.
ASC Regulations and Notices. cms.gov https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and/cms-1786-fc Accessed November 21, 2023
ASC specific rates will vary based on various specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

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