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 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 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 the device credit amount along with value code “FD” on the claim. If the device is furnished at no cost, report a charge of $0.00 for the device or, if the hospital’s billing system requires that a charge be entered, should submit a token charge (e.g. $1.00) to ensure proper claims adjudication:

<table>
<thead>
<tr>
<th>Value Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD</td>
<td>Credit received from the manufacturer for a replaced medical device</td>
</tr>
</tbody>
</table>

Also report the applicable condition code:

<table>
<thead>
<tr>
<th>Condition Code</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>49</td>
<td>Product Replacement within Product Lifecycle</td>
<td>Replacement of a product earlier than the anticipate lifecycle due to an indication that the product is not functioning properly</td>
</tr>
<tr>
<td>50</td>
<td>Product Replacement for Known Recall of a Product</td>
<td>Manufacturer or FDA has identified the product for recall and therefore replacement</td>
</tr>
</tbody>
</table>

AMBULATORY SURGERY CENTER (ASC) REPORTING
Use one of the following modifiers on the procedure code reported that was associated with use of the device:

<table>
<thead>
<tr>
<th>Modifier</th>
<th>When to Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>-FB</td>
<td>When device was replaced without cost or a full credit was received</td>
</tr>
<tr>
<td>-FC</td>
<td>When partial credit of 50% or more was received</td>
</tr>
</tbody>
</table>
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 DRG payment.
▪ Outpatient: Payment 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 Transmittal 1494 (starting on page 9)²
▪ Outpatient: See published Addendum P of each annual Outpatient Prospective Payment System (OPPS) Final Rule³
▪ ASC: See annual ASC FB/FC Device Adjustment Policy Files⁴

HOSPITAL BILLING OPTIONS FOR POLICY COMPLIANCE

There are two different billing options for the hospital while awaiting a manufacturer’s report on device credits:

▪ Submit claims without the required modifiers, receive payment in full, and then adjust the claim after the fact when the credit comes in; or
▪ Submit a clean claim—within timely filing requirements—once the hospital has the device credit information (this option delays the filing of the initial claim and requires tracking and follow-up)

UNREIMBURSED MEDICAL 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. co-pays, 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 (Monday-Friday, 8am-5pm Central Time).

DISCLAIMER

These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures.

CONTACT

For additional information, contact the Cardiac Rhythm & Heart Failure Reimbursement & Health Policy Team by phone at 866-877-4102 or by email at: rs.healthcareeconomics@medtronic.com.

REFERENCES

1. Medicare Claims Processing Manual Chapter 4, section 61.3.5 for outpatient instructions; Chapter 3, section 100.8 for inpatient instructions; and Chapter 14, section 40.8 for ASC instructions
3. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending
4. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html