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Complete Healthcare Compliance Manual
Revenue Cycle: Implantable Medical Device Credit Reporting

By Michael G. Calahan,[1] PA, MBA

What Is Implantable Medical Device Credit Reporting in Relation to the Revenue Cycle?

Certain medical devices might be implanted during inpatient or outpatient procedures. Such devices may require replacement because of defects, recalls, mechanical complications, or other factors. Under certain circumstances, federal regulations require reductions in Medicare payments for inpatient, outpatient, and ambulatory surgical center (ASC) claims for replacement of implanted devices due to recalls or failures.[2] It is important for compliance officers to be aware of the requirements and determinations related to replaced medical devices and whether Medicare payments for those devices were made in accordance with Medicare requirements. The area of reporting medical device credits is subject to enforcement interest and scrutiny by the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG), among other regulators.[3]

Since 2007, hospital providers have had to report implantable medical device credits to Medicare in relation to inpatient services; however, this particular Centers for Medicare & Medicaid Services (CMS) requirement remained a quiet niche area of compliance, hardly noticed by hospital revenue cycle staff.[4] One year later, in 2008, buoyed by this new reporting requirement's potential broad application, CMS expanded the scope of reportable device credit parameters and included implantable medical device credits related to select outpatient and ASC procedures.[5] There was a slow assimilation of this mandate industrywide. Today, although many more healthcare networks, hospitals, outpatient departments, and ASCs are aware of and strictly follow this reporting directive, confusion and uncertainty still linger, making this issue susceptible to scrutiny from federal auditors such as the HHS OIG. The continuing confusion generally includes these standard queries: What qualifies a credit to be reported? Is there a monetary threshold, a specific type of device, or a specific associated surgical procedure? The following information answers these perennial queries.

Basis for Medical Device Credit Reporting Obligation

Undergirded by the "Prudent Buyers Principle, in *The Provider Reimbursement Manual,Part 1*, Chapter 21, Sections 2102.1 and 2103 (A & B), and enforced through 42 C.F.R. § 413.9(a)-(c), reporting replacement device credits for certain implantable medical devices has now been widely promulgated. Few know of its basis in this somewhat buried principle. As an excerpt from the Prudent Buyers Principle in the manual states: "Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost-conscious buyer pays for a given item or service."[6]

Further, and specific to implantable medical devices, the manual states: "Another way to minimize cost is to obtain free replacements or reduced charges under warranties for medical devices. Any alert and cost-conscious buyer seeks such advantages, and it is expected that Medicare providers of services will also seek them."[7]

This passage firmly implies that if a reduced charge or warranty is to be gained, the onus is on the provider to

seek out those reductions and report them to Medicare.

Provider Obligations

As established by CMS as the baseline tenet for medical device credit reporting, the following must occur for applicable implantable medical devices undergoing *replacement*. If a healthcare provider receives a credit from a device manufacturer or vendor/supplier for a replacement device that is 50% or greater than the provider's cost for the replacement device, that credit must be reported to Medicare.[8] In essence, a healthcare provider is obliged to pass on the savings to Medicare. Further, in rare cases when a *newly implanted* device is part of an outpatient procedure and is provided to the hospital free of charge or at 100% credit (usually occurring in clinical trials), this cost savings must also be reported to Medicare.[9] Whether replacement devices or free-of-charge initially-placed devices, certain associated credits must be reported to Medicare via the (1) UB-04 hospital claim form and (2) CMS-1500 claim form for ASC claims, with the credit amount deducted from the device's line item charge.[10]

Qualifying Factors: Device-Dependent Procedures and Identifying Reportable Devices

The implantable medical device credit reporting directives pertain only to device-dependent procedures, also termed "device-intensive" procedures. This means the device would not be implanted without the surgical procedure, and/or the surgical procedure would not be performed without implanting the device. One is dependent upon the other.

In identifying reportable devices related to these device-dependent procedures, the device cost relative to the mean procedure cost (as assessed, predetermined, and published by CMS) must be "significant." The amount of the replacement-device cost relative to the predetermined total procedure cost is known as the device "offset" amount. CMS has defined this term as exceeding a device offset threshold of 30%.[11] (Note: Prior to 2019, this threshold was set at 40%). Additionally, devices must be:

- Approved by the Federal Drug Administration (FDA) for marketing and use, which includes investigational device exemption (IDE) devices classified by the FDA as a Category B device
- Considered an integral part of the service furnished
- Used for one patient only
- Used while coming into contact with human tissue
- Surgically implanted or inserted (either permanently or temporarily)[12]

Alternatively, devices must *not be*:

- Equipment, instruments, apparatus, or implements of the type for which depreciation and financing expenses are recovered as depreciable assets
- A material or supply that is furnished incident to a service (e.g., scalpel, surgical kit, sutures, or surgical clip other than a radiological site marker)[13]

For inpatients, these procedures (and their associated devices) are identified by Medicare Severity Diagnosis Related Groups (MS-DRGs) each fiscal year and made public via the Inpatient Prospective Payment System (IPPS) Final Rule, typically appearing within the rule's text in an MS-DRGs table format.[14] Device-dependent

procedures and their device offset amounts for outpatient and ASC settings are published each calendar year in the Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System Final Rule, typically summarized in an addendum in Excel format (i.e., not within the rule's main text).[15] Specifically for ASC, an additional addendum identifies all procedures approved to be performed within an ASC and includes a specific "payment indicator" denoting "device-dependent procedures approved for the ASC setting." For inpatient, outpatient, and ASC settings, this annually updated information is often (but not always) republished in official CMS change request/transmittal documents for the fiscal or calendar year in question. For inpatient services, the change request/transmittal is a one-time annual release; for outpatient and ASC, the change requests/transmittals are released quarterly.

Inform All Surgical Specialties in Hospital & ASC Settings

Implantable medical device-dependent procedures are performed in nearly all common clinical specialties within healthcare facility settings. Whether inpatient, outpatient, or ASC, there is probably a device-credit scenario of which providers should be aware. The surgical procedures include insertion of cardiac assist devices, pacemakers, and implantable cardioverter-defibrillator (ICD) systems; orthopedic surgeries involving total joint replacements; various neurosurgical procedures involving endovascular systems and neurostimulation devices; and urological, ophthalmological, and many other surgical specialties performing device-dependent procedures. As well, clinical trials conducted in nearly all surgical specialties can have device-dependent surgeries that require device credit reporting.