Medical Device Warranty Credits –

Discussion Sheet

##### How do you find the 2018 Medicare program OPPS device intensive procedures?

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-FC.html>

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##### How do you find the 2018 Medicare program IPPS device intensive procedures?

<https://www.gpo.gov/fdsys/pkg/FR-2017-08-14/pdf/2017-16434.pdf>

“We proposed to continue to include the existing MS–DRGs currently subject to the policy as displayed in a table in the proposed rule.” [Instead of an addendum] “we also will issue this final list of MS–DRGs subject to the payment policy for devices provided at no cost or with a credit for FY 2018 to providers through guidance and instructions in the form of a Change Request (CR).”

##### How do you scope device warranty compliance?

Example method:

Convert procedural codes under the Medicare policy to the related device types. A device types list (by category) can then offer a simplified method of flagging eligible devices in the EMR for return to manufacturer and warranty credit tracking based upon reason for removal.

##### What control mechanisms do you employ to assess the continuity of warranty activity for eligible devices?

Example metrics:

1. # of devices flagged for return in EMR vs. Logged as returned in ERP
2. # of vendor credit outcome responses over time
3. # of claims adjusted for credits >50% prior to internal checks

Perform routine internal checks to reconcile vendor reported warranty credits vs. claim adjustments.

##### Who owns medical device warranty credit workflows at your institution?

A dedicated resource within supply chain with indirect reporting to our compliance office provides support and oversight of this activity. Cross-departmental sign-off of an enterprise policy affirms the roles and responsibilities of each stakeholder group.

##### Who should control the return shipment of the device?

Hospital shipment allows for standardized return workflows including complete documentation of the patient/device and warranty claim follow-up activity. Vendor shipment may increase the risk of ‘out of sight, out of mind’ if appropriate documentation and follow-up is not performed.

##### How is warranty eligibility determined? Is there a need to ‘keep the vendor honest’?

In large part, warranty eligibility is determined by the vendor. However, hospital awareness of the general warranty parameters and provision of appropriate case details supports an accurate assessment. A decision to push back on a denied warranty claim is discretionary based on individual circumstances.

##### Which department is responsible for calculating the 50% rule? Or is there sole reliance on the vendor for this?

Accounts receivable (or similar team) may cross-match credits with explant return records. Common data elements may be the device serial number, return authorization number, or PO. A system tool (EMR or ERP) could house the related replacement device cost and support the 50% calculation.

##### What about explant procedures performed on patients who had a device implanted at another institution? Is the onus on the explanting institution to follow up with the manufacturer of explanted device?

Yes, the onus is on the explanting facility. If the explanted device may be eligible for warranty credit, it should be pursued with the vendor. If a credit is issued, the credit routes to the explanting facility. Replacements at ‘no charge’ may also apply.

##### How do you know if an explanted device may be eligible for warranty?

The vendor can be consulted. As a reasonable option, the hospital may elect to create a discrete field for explant reason in the EMR for all explants. If the combination of device type and reason for removal suggest potential warranty eligibility (e.g. pacemaker/early battery depletion, neuro stimulator/malfunction), an EMR prompt could occur to triage the device for return to vendor.