

Dear St. Jude Medical Customer,

This document summarizes Medicare requirements for the billing of device credits as it relates to the recent Advisory of the St. Jude Medical Riata® Silicon Defibrillation Lead by the U.S. Food and Drug Administration (FDA). Please use this document for guidance and contact the St. Jude Medical Reimbursement Hotline at 1-855-569-6430, or CRMD Reimbursement at kbolinger@sjm.com, with questions or concerns. We additionally recommend you review your Medicare Manual for detailed instructions.

Billing for Device Credits

Medicare regulations require institutions billing for no cost items to specify on the claim form if the product was of no cost because of recall or replacement due to warranty.

Effective January 2009, CMS regulation 67.2.1 affirmed that institutions are required to bill devices for no cost or full credit items with a 'FB' modifier to indicate that an item used in a procedure was furnished without cost to the provider. Medicare requires indication of device credits to communicate that the provider is not seeking payment for the no cost item.

Please see the table below for condition codes that are required to indicate warranty or product replacement due to recall. The FB Modifier and Condition code are required on the claim.

Condition Code		Description
49	Product Replacement within Product Lifecycle	A medical device is replaced before "end-of-life" because there is an indication that the device is not functioning properly. (This is a warranty situation.)
50	Product Replacement for Known Recall of a Product	A medical device is replaced because of a manufacturer or FDA recall.

These condition codes will be used by Medicare to track device replacements due to recall or warranty. Providers must report these condition codes on any inpatient or outpatient institutional (hospital) claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met. It is important for the institution to "hold the bill" until the adjudication process by St. Jude Medical has been completed as this will help to ensure the appropriate modifier is billed on the claim.

St. Jude Medical will adjudicate information by reviewing such information as fluoroscopy, x-ray films, interrogation strips and other evidence of lead dysfunction. Device credits will be issued for specific patients when a St. Jude Medical lead is replaced under the terms of the warranty.

Medical Necessity

Please keep in mind, medical necessity is required for all procedures. Standard of care and recommendations in the Physician Advisory provide guidance for routine services, fluoroscopy and invasive procedures. Medicare and most private payers do not reimburse “elective” procedures. If there is no indication for diagnostic imaging and or invasive procedures, it is highly unlikely to be covered by Medicare under the medical necessity statute¹. Additional regulations stipulate that if the patient does not sign an Advanced Beneficiary Notice (ABN) prior to any services, the provider cannot hold the patient responsible for the bill and thus the provider would be responsible for all charges.

Again, please feel to contact the Reimbursement Hotline at 855-569-6430 or myself with any billing questions.

Sincerely,



Karin Bolinger
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¹ National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § 1862(a)(1)(A).