| Policy Name | Recalled or Replaced Medical Devices  
(Applicable to Facility Services Only) |
|-------------|-----------------------------------------------------------------------------------|

**Summary**

Medica will cover the cost of medically necessary procedures to remove and replace recalled or replaced devices. Medica will not be responsible for the full cost of a replaced device if an inpatient or outpatient facility is receiving a partial or full credit for a device, due to either recall or service during the warranty period.

**Application**

This reimbursement policy applies to services reported using the UB-04 claim form or its electronic equivalent or its successor form.

**Policy Statement**

Medica will cover the cost of medically necessary procedures to remove and replace recalled or replaced devices subject to all applicable administrative, reimbursement, and member coverage rules, requirements, and limitations as defined in the provider contract and the administrative manual. Medica will not be responsible for the full cost of a replaced device if an inpatient or outpatient facility is receiving a partial or full credit for a device, due to either recall or service during the warranty period. Medica furthermore reserves the right to audit any claims related to such procedures. This policy applies to all Medica products.

When billing Medica in these situations, facilities should include the following information on inpatient and outpatient claims, as applicable:

- **Condition Code 49**, for product replacement within product lifecycle – This is a warranty situation involving the replacement of a product earlier than the anticipated lifecycle due to an indication that the product is not functioning properly.

- **Condition Code 50**, for product replacement for known recall of a product – This involves either the manufacturer or the U.S. Food and Drug Administration (FDA) identifying the product for recall, therefore requiring replacement.

- **Value Code FD**, for credit received from the manufacturer for a replaced medical device – The amount of the credit will be indicated in the amount portion for value code FD.

- **Modifier FB** – This hospital modifier is applicable when the item was provided without cost to provider, supplier or practitioner, or full credit was received for replaced device (examples are, but not limited to, covered under warranty, replaced due to defect, free samples).

- **Modifier FC** – This modifier is applicable when a partial credit was received for a replaced device.
Resources

- Centers for Medicare and Medicaid Services (CMS)
- Healthcare Common Procedure Coding System (HCPCS)
- Official UB-04 Data Specifications Manual

Effective Date

02/01/2009

Revision Updates

06/22/2017  Annual policy review
02/11/2016  Annual policy review
11/13/2014  Annual policy review