CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3181	**Date: January 30, 2015**
	Change Request 8961

SUBJECT: Implementation of New NUBC Condition Code "53" "Initial placement of a medical device provided as part of a clinical trial or a free sample"

I. SUMMARY OF CHANGES: This instruction implements Condition Code "53" for reporting on the outpatient hosptial claim.

EFFECTIVE DATE: July 1, 2015 - for claims received on or after
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2015

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/61.3.5/Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital or When the Hospital Receives a Full or Partial Credit for the Replacement Device Beginning January 1, 2014
R	32/67.2.1/Billing No Cost Items Due to Recall, Replacement, or Free Sample
R	32/68.4/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3181	Date: January 30, 2015	Change Request: 8961

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I. GENERAL INFORMATION

A. Background: Current system edits require a condition code to be billed for outpatient claims when the provider bills Value Code "FD" indicating that they have received a credit on the device. This Change Requests implements the newly created condition code "**53**" in order to allow providers to report device credits when the device is an initial placement of a medical device provided as part of a clinical trial or a free sample.

B. Policy: A new Medicare outpatient payment policy (see Federal Register December 10, 2013, pages 75005-75008) was implemented on January 1, 2014, requiring reporting of value code FD for medical devices furnished without cost to the hospital or when the hospital receives a full or partial credit for the device. However, hospitals must currently use either condition code 49 or 50 along with value code FD. Condition codes 49 and 50 only describe replacement devices. Condition Codes 49 and 50 do not describe a reduced cost initially implanted (non-replacement) devices, which are commonly supplied to Medicare beneficiaries, especially in the context of medical device clinical trials. Therefore, a new condition code is needed to describe initially implanted medical devices that are not replacement devices.

Under this policy, outpatient hospitals are required to report the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Medical Device) when the hospital receives a credit for a device listed in Table 31 of Federal Register December 10, 2013 that is 50 percent or greater than the cost of the device.

Also, hospitals are no longer required to append the ''FB'' or ''FC'' modifier when receiving a device at no cost or with a full or partial credit.

Additionally, CMS limits the OPPS payment deduction for device-intensive APCs to the total amount of the device offset when the ''FD'' value code appears on a claim.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
8961.1	Medicare Contractors shall accept the new Condition Code "53".	X				X				BCRC, CEM-A

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8961.2	Medicare System Maintainer Contractor shall update current system edits to allow Condition Code "**53**" in addition to Condition Codes "49" and "50" to be paired with Value Code "FD". "**53**" Initial placement of a medical device provided as part of a clinical trial or a free sample Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8961.3	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: Change Requests 3915, 4250, 5263, 5668, and 8653

V. CONTACTS

Pre-Implementation Contact(s): Fred Rooke, fred.rooke@cms.hhs.gov (For institutional claims processing questions contact) , John McInnes, John.McInnes@cms.hhs.gov (For policy questions contact)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

61.3.5 - Reporting and Charging Requirements When a Device is Furnished Without Cost to the Hospital or When the Hospital Receives a Full or Partial Credit for the Replacement Device Beginning January 1, 2014

(Rev.3181, Issued: 01-30-15, Effective: 07-01-15, Implementation: 07-06-15)

Effective January 1, 2014, when a hospital furnishes without cost *an initial placement of a medical device as part of a clinical trial or a free sample medical device or when a hospital furnishes without cost* a new replacement device or with a credit of 50 percent or more of the cost of a new replacement from a manufacturer, due to warranty, recall, or field action, the hospital must report the amount of the device credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Medical Device). Also effective January 1, 2014 hospitals must report one of the following condition codes when the value code "FD" is present on the claim:

- 49 Product Replacement within Product Lifecycle—Replacement of a product earlier than the anticipated lifecycle.

- 50 Product Replacement for Known Recall of a Product—Manufacturer or FDA has identified the product for recall and therefore replacement.

- *53 Initial placement of a medical device provided as part of a clinical trial or free sample— Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.*

No-Cost Device Coding

When a hospital furnishes a device for which it incurs no cost, (these cases include, but are not limited to, devices replaced under warranty, due to recall, or due to defect in a previous device; devices provided in a clinical trial; or devices provided as a sample) the hospital charge for a device furnished to the hospital at no cost should equal $0.00. However, some hospital's billing systems require that a charge be reported for separately billable codes in order for the claim to be submitted for payment, even items for which the hospital incurs no cost.

Hospitals paid under the OPPS that implant a device furnished at no cost to the hospital shall report a charge of zero for the device, or, if the hospital's billing system requires that a charge be entered, the hospital shall submit a token charge (e.g. $1.00) on the line with the device code.

CMS recognizes that showing a charge for a device that has been furnished without cost is not optimal, but showing a token charge in this circumstance will allow claims for reasonable and necessary services to be adjudicated.

67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample

(Rev.3181, Issued: 01-30-15, Effective: 07-01-15, Implementation: 07-06-15)

Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS) bill device HCPCS codes for no cost or full credit items with token charges in order for claims to pass OPPS claims processing edits that require certain devices to be billed with their associated procedures so that payment can be made.

Effective January 1, 2006, modifier –FB is used to indicate that an item used in a procedure was furnished without cost to the provider, and, therefore, it is not being charged to Medicare or the beneficiary. More information on billing HCPCS modifier –FB can be located in Chapter 4, §20.6.9 and 61.3.1 of this manual.

Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes are used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due to warranty for a malfunction or recall.

Table 1: New Condition Codes and Descriptions		
Condition Code		**Description**
49	Product Replacement within Product Lifecycle	*Replacement of a product earlier than the anticipated lifecycle.*
50	Product Replacement for Known Recall of a Product	*Manufacturer or FDA has identified the product for recall and therefore replacement.*

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty or recall. These condition codes will be used to track no cost/full credit devices replaced due to recall or warranty.

- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met.

NOTE: OPPS hospitals billing no cost/full credit devices must append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 1 above), in instances when claims processing edits require that certain devices be billed with their associated procedures. The modifier identifies the procedure code line for the no cost/full credit device, while the condition code explains if the device was provided free of cost due to warranty or recall.

Effective January 1, 2014, an additional new condition code was created for institutional use: 53 (Table 2). This new code is used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample.

Table 2: New Condition Codes and Descriptions		
Condition Code		***Description***
49	*Product Replacement within Product Lifecycle*	*Replacement of a product earlier than the anticipated lifecycle.*
50	*Product Replacement for Known Recall of a Product*	*Manufacturer or FDA has identified the product for recall and therefore replacement.*
53	*Initial placement of a medical device provided as part of a clinical trial or free sample*	*Code is for outpatient claims that have received a device credit upon initial medical device placement in a clinical trial or a free sample.*

- *Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty, recall, or free sample. These condition codes will be used to track no cost/full credit devices replaced due to recall, warranty, or free sample.*

- *Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty, recall, or free sample are met.*

NOTE: *OPPS hospitals billing no cost/full credit devices are no longer required to append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 2 above), in instances when claims processing edits require that certain devices be billed with their associated procedures.*

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

(Rev.3181, Issued: 01-30-15, Effective: 07-01-15, Implementation: 07-06-15)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.)

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- Appropriate HCPCS modifier:
    - Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or
    - Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or
    - QA modifier for claims with dates of service prior to January 1, 2008.
- Category B IDE number
- Charges for the device billed as covered charges

NOTE: *For claims prior to January 1, 2014*, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Effective January 1, 2014, if the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with condition code "53" and Value Code "FD". For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:

- 837 professional claim format (do not use 'CT' on the electronic claim) or,
- CMS-1500 paper form-place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims shall include (in either the primary/secondary positions):

- If ICD-9-CM is applicable, ICD-9 diagnosis code V70.7
- If ICD-10-CM is applicable, ICD-10 diagnosis code Z00.6
- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

Data	**CMS-1450**	**CMS-1500**	**837 institutional claim format and 837 professional claim format**
IDE #	Revenue Code Description field	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT."