CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 497 **Date: MARCH 8, 2005**

CHANGE REQUEST 3604

NOTE: Transmittal 488, dated March 4, 2005 is rescinded and replaced with Transmittal 497, dated March 8, 2005. There was a file inadvertently attached to the instruction. All other information remains the same.

SUBJECT: Billing for Implantable Automatic Defibrillators for Beneficiaries in a Medicare Advantage (MA) Plan and Use of the QR Modifier to Identify Patient Registry Participation.

I. SUMMARY OF CHANGES: This instruction announces that coverage of defibrillators for new indications is to begin for claims with dates of service on or after January 27, 2005. Once coverage is effective, payment for defibrillators covered for the new indications is to be made on a fee-for-service (FFS) basis when the beneficiary is under an MA plan. For the new indications, MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying the Part A or Part B deductibles (i.e., assume that the Part A or Part B deductible has been met). This instruction also clarifies that payment for previous, covered indications for defibrillators will be part of the MA capitated rates and not to be paid FFS for claims with dates of service on or after January 1, 2005, when the beneficiary is under an MA plan. In addition, it instructs contractors about the appropriate use of the KZ modifier and condition code 78 and supplies information that will be the basis of a future MedLearn Matters provider education article.

Medicare is also requiring that patients receiving a defibrillator for the new indications or for any indication that is for the primary prevention of sudden cardiac arrest (no history of induced or spontaneous arrhythmias) be enrolled in a data collection system to ensure the safety and quality of care. The QR modifier was created for use on Part B claims to identify services that are being covered under a clinical study. For defibrillator claims, the appropriate use of the QR modifier is to identify patients whose data is being submitted to a data collection system and is therefore meeting the coverage requirement for devices implanted for primary prevention of sudden cardiac arrest. Although coverage for the expanded indications is effective January 27, 2005, the QR should only be appended to claims submitted on or after April 4, 2005.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 27, 2005
IMPLEMENTATION DATE: January 27, 2005
IMPLEMENTATION QR MODIFIER: April 4, 2005

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Attachment – Business Requirements

Pub. 100-04	Transmittal: 497	Date: March 8, 2005	Change Request 3604

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SUBJECT: Billing for Implantable Automatic Defibrillators for Beneficiaries in a Medicare Advantage (MA) Plan and Use of the QR Modifier to Identify Patient Registry Participation.

I. GENERAL INFORMATION

A. Background: On August 22, 2003, Change Request (CR) 2880, (Transmittal AB-03-134), expanded coverage of implantable automatic defibrillators for certain indications effective October 1, 2003. CR 2880 established that payment for expanded coverage would be made on a fee-for-service (FFS) basis for covered defibrillator claims made on behalf of MA, formerly known as M+C, beneficiaries until Medicare capitation rates to MA organizations were adjusted to account for expanded coverage. On September 22, 2003, CR 2922, (Transmittal 4), also effective October 1, 2003, included minor corrections to a list of procedure codes in CR 2880. The CR 2922, contained all correct codes for billing implantable automatic defibrillators. It further:

1. Implemented systems changes to enable the automatic processing and payment of covered defibrillator claims on a FFS basis when the beneficiary is under an MA plan and the claims included either a KZ modifier attached to the defibrillator procedure codes or a condition code of 78;

2. Informed contractors of the actions they should take based on this information; and

3. Instructed providers to supply the KZ modifier or condition code 78 as appropriate to ensure proper adjudication of the covered defibrillator claims.

On July 23, 2004, CR 3301 (Transmittal 247), announced that, effective January 1, 2005, MA rates were appropriately adjusted to account for the defibrillator coverage described in CRs 2880 and 2922, and covered services for these indications will no longer be paid FFS when the beneficiary is under an MA plan.

However, Medicare is expanding coverage for implantable defibrillators for additional indications, effective January 27, 2005, and described below. Payment for defibrillators covered under the new indications, discussed in section B below, are not part of the capitated rates and are to be paid FFS when the beneficiary is under an MA plan.

In addition, Medicare is requiring that patients receiving a defibrillator for the new indications or for any other indication that is for the primary prevention of sudden cardiac arrest (no history of induced or spontaneous arrhythmias) be enrolled in a data collection system to ensure the safety and quality of care. The QR modifier was created for use on Part B claims to identify services that are being covered under a

clinical study. For defibrillator claims, the appropriate use of the QR modifier is to identify patients whose data is being submitted to a data collection system and is therefore meeting the coverage requirement for devices implanted for primary prevention of sudden cardiac arrest. Although coverage for the expanded indications is effective January 27, 2005, the QR should only be appended to claims submitted on or after April 1, 2005. The following ICD-9 diagnosis codes identify non-primary prevention (secondary prevention) patients:

- 427.1 ventricular tachycardia
- 427.41 ventricular fibrillation
- 427.42 ventricular flutter
- 427.5 cardiac arrest
- 427.9 cardiac dysrhythmia, unspecified

When any of these codes appear on a claim, the QR modifier is not required (these codes identify a patient receiving the device as secondary, not primary, prevention of sudden cardiac arrest). On the other hand, if none of the above ICD-9 diagnosis codes appear on the claim, patient data should be submitted to a data collection system and the QR modifier is required.

Part A inpatient claims that contain device implantation for secondary prevention indications should carry one of the above diagnosis codes. As a condition of primary prevention coverage, patient data must be submitted to a data collection system. Medicare will have the ability to review study data and compare patient participation against Medicare claims for primary prevention patients (claims lacking the above ICD-9 diagnosis codes).

The purpose of this CR is to:

1. Announce that coverage of defibrillators for the new indications is to begin for claims with dates of service on or after January 27, 2005;

2. Establish that, once coverage is effective, payment for defibrillators covered for these new indications is to be made on a FFS basis when the beneficiary is under an MA plan. MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying Part A or Part B deductibles (i.e., assume that the Part A or Part B deductible has been met);

3. Clarify that payment for previous, covered indications for defibrillators will be part of the MA capitated rates and not to be paid FFS for claims with dates of service on or after January 1, 2005, when the beneficiary is under an MA plan;

4. Instruct contractors about the appropriate use of the KZ modifier and condition code 78;

5. Instruct contractors about the appropriate use of the QR modifier for patients receiving a defibrillator as primary prevention of sudden cardiac arrest and that QR should only be appended to claims submitted on or after April 1, 2005; and

6. Supply information that will be the basis of a future MedLearn Matters provider education article.

B. Policy: Medicare pays for implantable cardiac defibrillators according to certain indications and data collection requirements. As explained in CR 3301, payment for services covered according to those indications established through CRs 2880 and 2922 will be part of the capitated rates for MA plans effective January 1, 2005, and for that reason, no longer paid FFS for beneficiaries under MA plans effective for claims with dates of service on or after that date.

However, Medicare is expanding coverage for implantable defibrillators to include new indications, effective January 27, 2005:

1. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) ≤ 35%;
2. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
3. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure;
4. Patients with NIDCM > 3 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35%.

Additional coverage requirements for each indication are specifically addressed in the National Coverage Determinations Manual, section 20.4. One of these requirements includes participation in a data collection system to determine safety and quality of care. Data collection is required for all the above indications and for any other indication that represents the primary prevention of sudden cardiac death. This primary prevention population is identifiable on claims through the absence of the following ICD-9 diagnosis codes:

- 427.1 ventricular tachycardia
- 427.41 ventricular fibrillation
- 427.42 ventricular flutter
- 427.5 cardiac arrest
- 427.9 cardiac dysrhythmia, unspecified

For these new indications, Medicare will pay for covered defibrillators on a FFS basis for claims for beneficiaries under MA plans through December 31, 2005. Providers will identify that they have rendered these services for these new indications to beneficiaries under an MA plan by adding a KZ modifier to the procedure code for claims billed to the carrier, or supplying a condition code of 78 for claims billed to the FI. Providers are not to use the KZ modifier or 78 condition code for defibrillator services rendered for other indications.

The processing of defibrillator claims for non-MA beneficiaries remains unchanged except to pay for claims for defibrillators rendered under the new coverage indications when appropriate.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to

supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.1	Contractors shall continue to pay for claims for covered services related to implantable defibrillators for indications in effect prior to January 27, 2005, for fee-for-service (FFS) beneficiaries.	X		X						
3604.2	Contractors shall pay for claims for covered services related to implantable defibrillators for the new indications effective for dates of service on or after January 27, 2005, for FFS beneficiaries.	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.3	Contractors shall deny claims for services related to implantable defibrillators for beneficiaries in an MA plan to include claims that meet the following criteria: • Contains condition code 78 or modifier KZ (or upon notification from CWF that the beneficiary is under an MA plan) • One of the procedure codes listed in Attachment 1 • The claim includes any of the following ICD-9 diagnosis codes: o 427.1 ventricular tachycardia o 427.41 ventricular fibrillation o 427.42 ventricular flutter o 427.5 cardiac arrest o 427.9 cardiac dysrhythmia, unspecified	X		X		X	X	X		
3604.4	FIs shall pay for inpatient hospital claims for covered services related to implantable defibrillators meeting any of the new indications effective January 27, 2005, for beneficiaries in an MA plan. That is, FIs shall pay for claims meeting all of the following conditions: • New indications effective January 27, 2005 • Date of service on or after January 27, 2005 • ICD-9 CM procedure code 37.94 (and other appropriate codes related to the new covered indications) • Condition code 78	X				X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.5	FIs shall pay for outpatient claims for covered services related to implantable defibrillators meeting any of the new indications effective January 27, 2005, for beneficiaries in an MA plan. That is, FIs shall pay for claims meeting all of the following conditions: • New indications effective January 27, 2005 • Date of service on or after January 27, 2005 • One of the HCPCS procedure codes listed in Attachment 1 (and other appropriate codes related to the new covered indications) • Condition code 78	X				X				
3604.6	Carriers shall pay for claims for covered services related to implantable defibrillators meeting any of the new indications effective January 27, 2005, for beneficiaries in an MA plan. That is, contractors shall pay for claims meeting all of the following conditions: • New indications effective January 27, 2005 • Date of service on or after January 27, 2005 • One of the procedure codes listed in Attachment 1 (and other appropriate codes related to the new covered indications) • KZ modifier			X			X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.7	Carriers shall pay for claims for covered services (as outlined in the NCDM §20.4) related to implantable defibrillators that are used in the primary prevention of sudden cardiac arrest. That is, contractors shall pay for claims meeting all of the following conditions: • Submitted on or after April 1, 2005 • One of the procedure codes listed in Attachment 1 • QR modifier • None of the following ICD-9 CM diagnosis codes: o 427.1 ventricular tachycardia o 427.41 ventricular fibrillation o 427.42 ventricular flutter o 427.5 cardiac arrest o 427.9 cardiac dysrhythmia, unspecified			X			X	X		
3604.8	FIs shall pay for outpatient claims for covered services (as outlined in the NCDM §20.4) related to implantable defibrillators that are used in the primary prevention of sudden cardiac arrest. That is, contractors shall pay for claims meeting all of the following conditions: • Claims submitted on or after April 1, 2005 • One of the procedure codes listed in Attachment 1 • QR modifier • None of the following ICD-9 CM diagnosis codes: o 427.1 ventricular tachycardia o 427.41 ventricular fibrillation o 427.42 ventricular flutter o 427.5 cardiac arrest o 427.9 cardiac dysrhythmia, unspecified • Condition code 78 (only applicable to MA claims)	X				X				

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.9	Beginning April 1, 2005, FIs shall deny outpatient claims that meet the requirements of 3604.8 but lack the QR modifier.	X				X				
3604.10	Beginning April 1, 2005, carriers shall deny claims that meet the requirements of 3604.7 but lack the QR modifier.			X			X	X		
3604.11	FIs shall not apply Part A deductible for claims for beneficiaries in MA plans containing all of the following criteria: • Services related to indications effective January 27, 2005 • Dates of service on or after January 27, 2005, • Condition code 78, • One of the procedure codes listed in Attachment 1 (and other appropriate codes related to the new covered indications)	X								
3604.12	Carriers shall not apply Part B deductible for claims for beneficiaries in an MA plan containing all of the following criteria: • Services related to indications effective January 27, 2005, • Dates of service on or after January 27, 2005, • Modifier KZ, • One of the procedure codes listed on Attachment 1 (and other appropriate codes related to the new covered indications)			X						
3604.13	Contractors shall apply coinsurance to claims for risk managed care beneficiaries who receive covered services related to implantable cardiac defibrillators for the new coverage indications with dates of service on or after January 27, 2005.	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.14	FIs shall educate providers to only include condition code 78 for implantable cardiac defibrillator claims meeting any of the new coverage indications effective January 27, 2005, (as outlined in the NCDM, section 20.4) and when none of the following ICD-9 diagnosis codes are reported: • 427.1 ventricular tachycardia • 427.41 ventricular fibrillation • 427.42 ventricular flutter • 427.5 cardiac arrest • 427.9 cardiac dysrhythmia, unspecified.	X								
3604.15	Carriers shall educate providers to only include modifier KZ for implantable cardiac defibrillator claims meeting any of the new coverage indications effective January 27, 2005, (as outlined in NCDM, section 20.4) and when none of the following ICD-9 diagnosis codes are reported: • 427.1 ventricular tachycardia • 427.41 ventricular fibrillation • 427.42 ventricular flutter • 427.5 cardiac arrest • 427.9 cardiac dysrhythmia, unspecified.			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3604.16	FIs and carriers shall educate providers to include modifier QR only for claims submitted on or after April 1, 2005, meeting the following: • One of the procedure codes listed in Attachment 1 • Submitted on or after April 1, 2005 • None of the following ICD-9 diagnosis codes are reported: o 427.1 ventricular tachycardia o 427.41 ventricular fibrillation o 427.42 ventricular flutter o 427.5 cardiac arrest o 427.9 cardiac dysrhythmia, unspecified.	X		X						
3604.17	Standard systems should not create any front-end edits for requirements 3604.11 and 3604.12.					X	X	X		

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
3604.16	Additional coding guidance, as appropriate, should be provided.

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 27, 2005 **Implementation Date:** January 27, 2005 **Implementation QR Modifier:** April 4, 2005 **Pre-Implementation Contact(s):** **Coverage:** JoAnna Baldwin, 410-786-7205**,** jbaldwin@cms.hhs.gov **Part A:** Joe Bryson, 410-786-2986, jbryson2@cms.hhs.gov **Part B:** Claudette Sikora, 410-786-5618**,** csikora@cms.hhs.gov **Post-Implementation Contact(s):** Regional office	**Medicare contractors shall implement these instructions within their current operating budgets.**

***Unless otherwise specified, the effective date is the date of service.**

Attachment

Attachment 1

Procedure Codes Billable to FIs

The G codes listed below are payable under OPPS effective October 1, 2003. These G codes are not payable under the Medicare Physician Fee Schedule and, therefore, should not be billed to Medicare carriers.

- G0297
- G0298
- G0299
- G0300

The following ICD-9 CM procedure code should be billed to fiscal intermediaries on 11X type of bills:

37.94

Procedure Codes Billable to Carriers

- 33249