



Related MLN Matters Article #: MM3604

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

#### Key Words

CR3604, MM3604, Implantable, Defibrillators, MA, QR, CR2880, CR2992, CR3301, MM3301, R497CP, FSS, 427.1, 427.2, 427.5, 427.9, IDE, MM4273, CR4273

#### Provider Types Affected

All Medicare providers billing either a Medicare Carrier or Fiscal Intermediary (FI) for Implantable Automatic Defibrillators for Medicare beneficiaries who are members of MA plans

#### Key Points

- The effective date of the instruction is January 27, 2005.
- The implementation date is January 27, 2005.
- The implementation date for the QR modifier is April 4, 2005.
- The national coverage for implantable automatic defibrillators is being expanded to include the following new indications:
  - 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)  $\leq$  35%;
  - Patients with nonischemic dilated cardiomyopathy (NIDCM)  $>$  9 months, NYHA Class II and III heart failure, and measured LVEF  $\leq$  35%;
  - Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy device and have NYHA Class IV heart failure;
  - Patients with NIDCM  $>$  3 months, NYHA Class II or III heart failure, and measured LVEF  $\leq$  35%.
- Defibrillator use for these new indications is not part of the capitated rates and is to be paid Fee-For-Service (FFS) when the beneficiary is under a MA plan.

- Payment for previously covered indications for defibrillator use, i.e., those indications approved prior to January 27, 2005, will be part of the MA capitated rates and are not to be paid on a FFS basis for beneficiaries under a MA plan.
- Data must be collected and reported through an approved data collection mechanism for beneficiaries that receive an implantable automatic defibrillator for the primary prevention of sudden cardiac death.
- The following is a summary of the history of indications for implantable defibrillators leading up to CR3604:
  - **July 1, 1991** - Documented episode of cardiac arrest due to Ventricular Fibrillation (VF), not due to a transient or reversible cause;
  - **July 1, 1999** - Documented sustained Ventricular Tachyarrhythmia (VT), either spontaneous or induced by an Electrophysiology (EP) study, not associated with an acute MI and not due to a transient or reversible cause; documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy;
  - **October 1, 2003** - Coverage was expanded to include coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction  $\leq 0.35$ , and inducible, sustained VT or VF at an EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
- The following summarize the history of payment policies for implantable defibrillators leading up to CR 3604:
  - **October 1, 2003 (CRs 2880 & 2992)** - For covered defibrillator claims made on behalf of MA (formerly known as M+C) beneficiaries, payment for the expanded coverage (above) would be made on a FFS basis until Medicare capitation rates to MA organizations were adjusted to account for expanded coverage.  
  
System changes were implemented to enable the automatic processing and payment of covered defibrillator claims on a FFS basis when the beneficiary was under a MA plan and the claims included either a KZ modifier attached to the defibrillator procedure codes when billing a carrier or a condition code of 78 when billing a FI.
  - **January 1, 2005 (CR3301)** - Because MA rates have been appropriately adjusted to account for the defibrillator coverage described in CRs 2880 and 2992, covered services for the indications in these CRs will no longer be paid FFS when the beneficiary is under a MA plan.
  - **January 27, 2005 (CR3604)** - CMS announces expanded coverage for implantable defibrillators for additional indications, as previously indicated.
- Providers should include a KZ modifier for carrier claims and a condition code of 78 for FI claims until the MA capitated rates are adjusted to indicate that the beneficiary is under an MA plan and the services provided are for one of the new indications.
- MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying Part A or Part B deductibles (so providers should assume that the Part A or Part B deductible has been met).
- For indications effective after January 27, 2005, patients must not have:

- Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
  - Had a coronary artery bypass graft or Percutaneous Transluminal Coronary Angioplasty within the past 3 months;
  - Had an acute MI within the past 40 days;
  - Clinical symptoms or findings that would make them a candidate for coronary revascularization; or
  - Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than one year.
- All patients considered for implantation of a defibrillator must be able to give informed consent.
  - Myocardial infarctions must be documented and defined according to the consensus document of the Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction.
  - Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography.
  - Providers must be able to justify the medical necessity of devices other than single lead devices.
  - This justification should be available in the medical record.
  - 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 a previous cardiac arrest]) must be enrolled in either a Food and Drug Administration-approved Category B Investigational Device Exemption clinical trial, a trial under the Centers for Medicare & Medicaid Services Clinical Trial Policy, or a qualifying data collection system including approved clinical trials and registries to ensure the safety and quality of care.
  - CMS will maintain an implantable automatic defibrillator registry using a mechanism that Medicare participating hospitals already use to submit quality data to the Quality Improvement Organizations (QIOs).
  - Hospital staff will fill out the data collection form (supplied by CMS) using the Implantable Cardiac Defibrillator (ICD) Abstraction Tool and transmit it via the Quality Network Exchange to the QIO.
  - Iowa Foundation for Medical Care will collect and maintain registry data and the QIOs will be able to ensure the quality of the data by sampling charts.
  - Additional information on the ICD Abstraction Tool is available through a previously issued Special Edition MLN Article (SE0517).
  - The QR modifier was created for use on Part B claims to identify protocol covered services.
  - The appropriate use of the QR modifier, in defibrillator claims, is to identify patients whose data is being submitted to a registry and to document meeting the coverage requirement for devices implanted for primary prevention of sudden cardiac arrest.
  - Providers should only append the QR modifier on claims submitted on or after April 1, 2005.
  - This modifier is not required when International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes 427.1 ventricular tachycardia; 427.41 ventricular fibrillation; 427.42 ventricular flutter; 427.5 cardiac arrest; 427.9 cardiac dysrhythmia, unspecified appear on the claim, as

these codes identify a patient receiving the device as secondary, not primary prevention, of sudden cardiac arrest.

**Note:** MM4273 added two new ICD-9-CM codes (**996.04 and V53.32**) to the list of codes that do not require the use of the QR modifier for claims processing (effective on or after April 1, 2006, for claims with dates of service on and after April 1, 2005). See the Important Links section below.

- If none of the above ICD-9-CM diagnosis codes applies to the device implant, patient data should be submitted to a registry and the QR modifier is required for claims submitted on or after April 1, 2005.
- Providers billing **Medicare FIs** should:
  - Use the following G codes (payable under Outpatient Prospective Payment System effective October 1, 2003): G0297, G0298, G0299, and G0300;
  - Use the following ICD-9-CM procedure code on 11X type of bills: 37.94.
- Providers billing **carriers** should use procedure code 33249.

## Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3604.pdf> on the CMS website.

The official instruction (CR3604) regarding this change may be viewed at

<http://www.cms.hhs.gov/transmittals/downloads/R497CP.pdf> on the CMS website.

If providers have any questions, they may contact their carrier or FI at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

Providers may want to review the following related MLN Matters articles:

- MM4273 (Modification to QR Modifier Edit for Automatic Implantable Cardiac Defibrillator (ICD) Services) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm4273.pdf>, which added two new ICD-9-CM codes (addressing Implantable Cardiac Defibrillator replacement due to instrument recall or device complication) to the list of codes that do not require the use of the QR modifier for claims processing (effective on or after April 1, 2006, for claims with dates of service on and after April 1, 2005);
- MM3301 (Coverage by Medicare Advantage Organizations for National Coverage Determination (NCD) Services Not Previously Included in the Medicare Advantage's Capitated Rates) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3301.pdf>; and
- SE0517 (Tool Available for Registering Patients with Implantable Cardioverter Defibrillators) at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0517.pdf> on the CMS website.