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Related Change Request (CR) #: 3604

Related CR Release Date: March 8, 2005

Effective Date: January 27, 2005

Related CR Transmittal #: R497CP

Implementation Date: January 27, 2005; Implementation Date for QR Modifier: April 4, 2005

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

Note: This article was revised on August 21, 2007, to add a reference to MLN Matters article MM4273 (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm4273.pdf>). MM4273 added two new ICD-9-CM codes (addressing Implantable Cardiac Defibrillator replacement due to instrument recall or device complication) to the list of codes (see page 6) 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).

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 Medicare Advantage plans

Provider Action Needed



STOP – Impact to You

Be aware that CMS is expanding the set of medical indications for the use of implantable automatic defibrillators and this instruction discusses the impact of this change for beneficiaries who are members of a MA plan and receive these services.



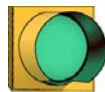
CAUTION – What You Need to Know

CR 4097 implements the Negotiated Rulemaking agreement to automatically consider all diagnosis codes reported on claims. Effective January 27, 2005, CMS is expanding national coverage for implantable automatic defibrillators by including the following new indications:

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- 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 CMS coverage requirements for a cardiac resynchronization therapy (CRT) 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%. (See Note below)



GO – What You Need to Do

Make sure that your billing staffs are aware of these new indications and also the basis for billing Medicare.

Note: For beneficiaries under a MA plan, payment for defibrillator use effective January 27, 2005 is different for these new indications than it is for previously covered indications. When the beneficiary is under an MA plan, defibrillator use for these new indications is not part of the capitated rates and is to be paid Fee-For-Service (FFS). However, payment for previously covered indications for defibrillators implanted in these beneficiaries will be part of the MA capitated rates and is not to be paid FFS. In addition, data must be collected and reported through an approved data collection mechanism for beneficiaries who receive an implantable automatic defibrillator for the primary prevention (as opposed to secondary prevention) of sudden cardiac death. The above indications are considered primary prevention indications. Additional information regarding the ICD Abstraction Tool is available through a previously issued Special Edition MLN Matters Article (SE0517, which is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0517.pdf> on the CMS website.

Background

The Implantable Automatic Defibrillator, consisting of a pulse generator and electrodes for sensing and defibrillating, is an electronic device designed to detect and treat life-threatening tachyarrhythmias. Medicare pays for the use of these defibrillators only for certain clinical indications.

Here is a synopsis of the history of indications and payment policies (indicating the effective dates) for implantable defibrillators, leading up to Change Request (CR) 3604:

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Indications

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 Myocardial Infarction (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 ≤ 0.35 , and inducible, sustained VT or VF at 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).

Payment Policies

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.

Also at this time, 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 fiscal intermediary.

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.

Now in CR 3604, Medicare announces expanded coverage for implantable defibrillators for additional indications, effective January 27, 2005. These indications include the following:

- 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 $\leq 35\%$;

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- Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) 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%.

Please note this additional information:

- Since this new coverage exceeds the significant cost threshold for managed care organizations, services related to the newly covered indications will be paid only on a fee-for-service basis for patients enrolled in a managed care plan. To reiterate, 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. (Coverage guidelines can be found in the *National Coverage Determination Manual* (NCDM), Section 20.4.).
- As a reminder, remember that MA plan beneficiaries are responsible for paying applicable coinsurance, but are not responsible for paying Part A or Part B deductibles (so you should assume that the Part A or Part B deductible has been met). To indicate that the beneficiary is under an MA plan and the services provided are for one of the new indications, providers are to include a KZ modifier for carrier claims and a condition code of 78 for fiscal intermediary claims until the MA capitated rates are adjusted.
- 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.
- Except for reimbursing for the use of the defibrillators for the new indications, the processing of defibrillator claims for non-MA beneficiaries remains unchanged.
- 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 (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) 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 1 year.

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- 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.

You should also be aware that 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 a previous cardiac arrest]) be enrolled in either a Food and Drug Administration-approved Category B Investigational Device Exemption (IDE) 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.

Initially, 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 ICD Abstraction Tool and transmit it via QNet (Quality Network Exchange) to the QIO.

Iowa Foundation for Medical Care (IFMC) will collect and maintain registry data and the QIOs will be able to ensure the quality of the data by sampling charts. Additional information regarding the ICD Abstraction Tool is available through a previously issued Special Edition MLN Article (SE0517), which is available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0517.pdf> on the CMS website.

Additional data collection systems (trials or registries) addressing at a minimum the hypotheses specified in this decision must meet the following basic criteria:

- Written protocol on file,
- Institutional Review Board review and approval,
- Scientific review and approval by two or more qualified individuals who are not part of the research team, and
- Certification that investigators have not been disqualified.

For purposes of this coverage decision, CMS will determine whether specific registries or clinical trials meet these criteria.

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Also, remember that 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 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.

On the other hand, if none of the above ICD-9 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.

One final note:

- Providers billing Medicare Fiscal Intermediaries should:
 - Use the following G codes (payable under OPPS effective October 1, 2003): G0297, G0298, G0299, and G0300.
 - **Note:** These G codes are not payable under the Medicare Physician Fee Schedule and, therefore, should not be billed to Medicare carriers.
 - Use the following ICD-9-CM procedure code on 11X type of bills: 37.94
- Providers billing carriers should use procedure code 33249.

Additional Information

You can find more information about Billing for Implantable Automatic Defibrillators for Beneficiaries in an MA Plan by going to <http://www.cms.hhs.gov/Transmittals/downloads/R497CP.pdf> on the CMS website.

Finally, if you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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