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Provider Education Article – National Coverage Determination – Implantable Automatic Defibrillators

This provider education article discusses the background of the National Coverage Determination (NCD) to expand coverage of implantable automatic defibrillators for services rendered on or after October 1, 2003, coverage guidelines, billing instructions for providers who render services to managed care patients, and billing instructions for providers who render services to fee-for-service patients. .

Background

The NCD will be effective on October 1, 2003 to expand coverage of implantable automatic defibrillators for Medicare managed care and fee-for-service patients. Providers will be reimbursed for services provided to managed care patients for implantable automatic defibrillators that fall under the expanded coverage indications effective October 1, 2003, according to the NCD on a fee-for-service basis until capitation rates are adjusted to account for this expanded coverage.

Coverage Guidelines

The following services are covered when rendered on or after July 1, 1991:

• Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause;

• 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 indications with a high risk of life-threatening VT, such as long QT syndrome or hypertropic cardiomyopathy;

As stated in the NCD, the following indications will be covered when rendered on or after October 1, 2003:

• Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction ¡Ü 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.);

• Documented prior MI and a measured left ventricular ejection fraction ¡Ü 0.30 and a QRS duration of > 120 milliseconds. Patients must not have:

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a) New York Heart Association classification IV;

b) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;

c) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within past 3 months;

d) Had an enzyme-positive MI within past month;

e) Clinical symptoms or findings that would make them a candidate for coronary revascularization; or

f) Any disease, other than cardiac disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.

As stated in the NCD, effective October 1, 2003, the following additional coverage

guidelines apply:

• All patients considered for implantation of a defibrillator must not have irreversible brain damage, disease, or dysfunction that precludes the ability to give informed consent;

• MIs must be documented by elevated cardiac enzymes or Q-waves on an electrocardiogram. Ejection fractions must be measured by angiography, radionuclide scanning, or echocardiography; and

• All other indications remain noncovered except in Category B IDE clinical trials (60 CFR 48417) or as a routine cost in clinical trials defined under CIM 30-1.

NOTE: Refer to Coverage Issues Manual, Section 35-85 (revisions effective October 1, 2003).

Billing Instructions for Providers Who Render Services to Managed Care Patients

The following instructions apply to providers who render expanded implantable automatic defibrillator services to managed care patients:

• Providers are encouraged not to submit claims for services rendered on or after October 1, 2003, because Medicare will not be able to process the claims until January 5, 2004.

• Physicians must use modifier KZ (new coverage not implemented by managed care) when billing for services rendered on and after October 1, 2003.

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• Providers billing fiscal intermediaries on or after October 1, 2003, must use condition code 78 (payment for coverage not implemented by HMO).

• Providers who are paid under the Outpatient Prospective Payment System (OPPS) must bill all services related to this expanded coverage on one claim and for the same date of service, using condition code 78.

• Providers billing carriers and providers who are paid under the OPPS must split the bills if they overlap September 2003 and October 2003.

• Patients who receive these services must pay any applicable coinsurance amounts.

• For services rendered to managed care patients whose indications fall outside this expanded coverage, providers must not bill using condition code 78 or modifier KZ.

Billing Instructions for Providers Who Render Services to Fee-for-Service Patients

The following instructions apply to providers who render expanded implantable automatic defibrillator services to fee-for-service patients:

• Claims for these services cannot be billed using modifier KZ, condition code 78, or for services outside of this expanded coverage.