



Medicare Plan Policy Group

The Center for Beneficiary Choices

Date: March 18, 2005

To: Medicare Advantage Organizations

From: Director, Medicare Plan Policy Group

On January 27, 2005, CMS issued a National Coverage Determination (NCD) regarding expanded Medicare coverage of Implantable Cardioverter Defibrillators (ICDs) to prevent sudden death in people with heart disease, effective for services performed on or after January 27, 2005. See the enclosed Pub. 100-03 Medicare National Coverage Determination, (document R29NCD.pdf) for coverage criteria.

The purpose of this memo is to announce that we have determined that this NCD meets the significant cost threshold described in section 1852(a)(5) of the Social Security Act and 42 CFR 422.109 of the Medicare regulations. As stated in 42 CFR 422.109(b), if CMS determines and announces that an NCD meets the significant cost criteria, a Medicare Advantage Organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service.

Background on Coverage

As described further in the enclosed NCD manual instruction, the ICD is used for primary prevention of sudden cardiac death. The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating. CMS initially provided limited coverage of implantable defibrillators in 1986. The policy over the years has expanded. In 2003, the NCD on ICDs expanded coverage to specific patient populations for both primary and secondary prevention of sudden cardiac death. CMS has now determined that implantable cardioverter defibrillators are reasonable and necessary for additional indications. A summary of this expansion for ICDs can be found at www.cms.hhs.gov/coverage/download. Under "General Information," click on "Summary of Coverage of ICDs."

Medicare Payment for Expanded ICD Coverage

CMS will make payments on a fee-for-service basis for ICD costs *meeting the expanded coverage criteria* for services provided on or after January 27, 2005 and through December 31, 2005. Medicare Advantage Organizations will not be liable for payment for costs relating

directly to the provision of services related to ICDs under these expanded coverage criteria until their payments can be appropriately adjusted to take into account the cost of this NCD. Medicare fiscal intermediaries and carriers will make payments on behalf of Medicare Advantage organizations directly to providers of ICDs meeting these expanded coverage criteria in accordance with Medicare payment rules. Medicare Advantage enrollees will be liable for any applicable coinsurance amounts under Original Medicare but are not responsible for paying the Part A or Part B deductibles.

Medicare Advantage Organizations should notify plan members of this new coverage and financial liability on enrollees in their next regularly scheduled beneficiary communication. In addition, as stated in regulations at 42 CFR 422.109(c), costs for NCD services that meet the significant cost threshold for which CMS intermediaries and carriers will not make payment and are the responsibility of the Medicare Advantage Organization include services necessary to diagnose a condition covered by the NCD, most services furnished as follow-up care to the NCD service, any service that is already a Medicare-covered service and included in the annual Medicare Advantage capitation rate or previously adjusted payments and any service, including the costs of the NCD service to the extent the Medicare Advantage Organization is already obligated to cover it as an additional benefit under section 422.312 or supplemental benefit under section 422.102.

Medicare Claims Processing Instructions

Enclosed are claims processing instructions for claims for ICDs for Medicare Advantage plan enrollees. It instructs contractors to use modifier KZ and hospitals to use condition code 78 when billing for services for ICD for patients in a Medicare Advantage plan when the conditions fall under the new indications, which became effective January 27, 2005. 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 the 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 because Medicare will not be able to process the claims until that date. Also enclosed are Medicare Claims Processing Manual instructions Pub. 100-04 (document named R497CP.pdf) for your information.

If you need additional information, please contact LaVern Ware at Lware@cms.hhs.gov or at 410-786-5480.

Sincerely,

/S/

Tom Hutchinson

Enclosures:

NCD manual instructions (R29NCD.pdf)

Medicare Claims Processing Manual Instructions (R497CP.pdf)