DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
Medicare Advantage Group

7500 Security Boulevard
Baltimore, Maryland 21244

Date: July 5, 2006

To: Medicare Advantage Organizations

From: David A Lewis, Acting Director
Medicare Advantage Group

Subject: National Coverage Determinations – Implantable Cardioverter Defibrillators

On January 27, 2005, CMS issued a National Coverage Determination (NCD) regarding expanded Medicare coverage of Implantable Cardioverter Defibrillators (ICDs coded 37.94) to prevent sudden death in people with heart disease, effective for services performed on or after January 27, 2005. Since this NCD met the significant cost threshold as described in section 1852(a)(5) of the Social Security Act and 42 CFR 422.109 of the Medicare regulations, CMS made payments on a fee-for-service basis for the ICD costs meeting the expanded coverage criteria for services provided on or after January 27, 2005 through December 31, 2005. Medicare Advantage Organizations (MAOs) were not liable for payment for costs relating directly to the provision of services related to the ICDs until their payments were appropriately adjusted to take into account the cost of the NCD. The rates of the MAOs were appropriately adjusted effective January 1, 2006.

This letter addresses the inquiry which has been raised regarding the payment responsibility for the CRT-D device (00.51) versus the AICD device (37.94) for which there is a national coverage determination. CMS recognizes that since the change request announcing the national coverage of the AICD device (coded 37.94) included in the expanded criteria individuals who were eligible for a resynchronization device, that it may have become confusing. However, all disseminated documents clearly specified the code for the device that met the significant cost criteria.

Although the CRT-D (00.51) device was not analyzed for **national coverage** consideration, CRT-Ds may be determined by providers, on a case-by-case basis, to be "reasonable and necessary" as well as the most appropriate device for a beneficiary for improving his or her health. Most covered benefits are local coverage determinations. Further, an un-posted local coverage determination in your respective geographic location does not mean that it is an uncovered benefit by your local contractor since a specific exclusion has not been made. Guidance on this may be found in Chapter 4 of the Medicare Managed Care Manual – Section 10.9 which states the following:

"Medicare payment is contingent upon a determination that:

- A service meets a benefit category;
- Is not specifically excluded from coverage; and
- The item or service is "reasonable and necessary."

Lastly, contractors may apply LCDs to claims on either a prepayment or post payment basis (please see Chapter 13 Local Coverage Determinations of the Program Integrity Manual – Internet Only Manual (IOM) #100-08).

Thus, since this particular CRT-D device (00.51) was not the device analyzed and determined to have met the significant cost criteria in the approved NCD, the Medicare Advantage plans are responsible for payment of this device when it has been found it to be medically necessary for an eligible beneficiary.

If you have any questions concerning this NCD, contact Lavern Ware at 410-786-5480 or via email at lavern.ware@cms.hhs.gov .