

Case Study: Automatic Implantable Defibrillators

The experience of Automatic implantable cardioverter/defibrillators (AICDs) highlights the need for Medicare to update its coverage policies and payment system frequently to keep pace with medical innovation, as well as the importance of employing valid external as well as internal data in making payment adjustments.

AICDs are life-saving devices that treat patients' irregular heart beats and have dramatically improved patient care since the mid-1980s. These technologies, however, have experienced considerable delays in gaining appropriate Medicare coverage and adequate payment in the hospital inpatient setting. These delays have resulted in obstacles to patient access.

Medicare's coverage policy for AICDs has not kept up with expanding patient indications. It has taken HCFA at least 18 months to make changes to the Medicare coverage policy for AICDs. From 1991 to 1998 the policy remained static even as the technology and indications advanced considerably.

One or both of the components in an AICD (the pulse generator and leads) must periodically be replaced. Since pulse generator batteries have a limited life-span, so-called "single-component" replacement procedures typically involve replacement of the generator rather than the leads.

Medicare reimbursement for single-component procedures historically has been low. Between 1989 and 1992 in particular, Medicare payment was inadequate. HCFA initially refused to adjust payment because it was relying solely on its internal data, which in this case was seriously flawed.

After an external analysis showed that the Health Care Financing Administration's data "seriously understated" the average charges for single-component procedures, the agency reexamined its policy. Finally, four years later, HCFA implemented improved reimbursement for the procedure.

AICD manufacturers remain concerned that as the technology continues to advance rapidly, obtaining appropriate Medicare reimbursement updates will again prove difficult.