

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201
Office of Communications



MEDICARE NEWS

FOR IMMEDIATE RELEASE
July 7, 2011

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Medicare expands coverage for patients with pacemakers that are FDA-approved for use with MRI exams

The Centers for Medicare & Medicaid Services (CMS) today expanded Medicare coverage of Magnetic Resonance Imaging (MRI) for beneficiaries with implanted pacemakers when used according to FDA-approved labeling in an MRI environment. A final National Coverage Determination (NCD) posted today provides access to the MRI environment for patients with FDA-approved pacemakers.

On February 8, the Food and Drug Administration (FDA) approved the RevoMRI SureScan Pacing System, which is designed for use in the MRI environment for certain MRI exams. Currently, there are no other pacemakers or implantable cardioverter defibrillators that are FDA-approved for use in the MRI environment.

“This swift action by CMS provides patients who need a pacemaker with greater access to MRI exams,” said Donald M. Berwick, M.D., CMS administrator. “The expedited review of this decision demonstrates our commitment and support of new technology that will help improve the health of our beneficiaries.”

MRI is a noninvasive method of imaging that has the capability of demonstrating a wide variety of soft-tissue lesions in various parts of the body. It is used to diagnose many medical conditions, such as cancer, and is used to look at various parts of the body, including the head, central nervous system, and the spine. MRI also has advantages over other imaging techniques such as computed tomography (CT) and conventional radiographs, including no radiation exposure and easier visibility of soft tissue.

However, MRI exposes the patient to high magnetic and radio-frequency fields that may cause the movement or heating of implanted medical devices that are ferromagnetic (e.g. surgical clips)

or that have ferromagnetic components (e.g. pacemakers, prostheses). The American College of Radiology's (ACR) guidance document on safe MRI Practices (Kanal, 2007) explicitly discusses the need to address potential risks of exposure for patients that may have ferromagnetic foreign bodies or implants.

The final coverage policy issued today follows a proposed decision issued in April 2011. The final decision memorandum is available on the CMS website at [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NcaName=Magnetic%20Resonance%20Imaging%20\(MRI\)%20\(3rd%20Recon\)&bc=ACAAA AAAIAAA&NCAid=252&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NcaName=Magnetic%20Resonance%20Imaging%20(MRI)%20(3rd%20Recon)&bc=ACAAA AAAIAAA&NCAid=252&).