



March 31, 2011

Louis Jacques, MD  
Director, Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
Office of Clinical Standards and Quality  
Coverage and Analysis Group  
7500 Security Blvd  
Mail Stop C1-09-06  
Baltimore, MD

*SUBMITTED ELECTRONICALLY*

**RE: National Coverage Analysis (NCA) Tracking Sheet for Magnetic Resonance Imaging (MRI) (CAG-00399R3)**

Dear Dr. Jacques:

The North American Society for Cardiovascular Imaging (NASCI) and the American College of Radiology (ACR) has reviewed the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) with plans for Continuing Evidence Development (CED) and appreciates this opportunity to provide comment. Our societies agree that patients with an implanted MRI compatible pacemaker may undergo MRI scanning if 1) clinically indicated under the recommended guidelines of the manufacturer, 2) that MRI scanning should be done only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand, and 3) that other monitoring, follow-up or precautionary measures *as documented in the operating instructions of the Food and Drug Administration (FDA)-approved device*, be adhered to. However, we oppose Coverage with Evidence Development (CED). We support following the FDA guidelines and recommend that the NCD state these guidelines must be followed.



NASCI and ACR believe that query 1 stating, “*Do the results of MRI in PM/ICD beneficiaries with implanted cardiac devices affect decision making related to: a. Clinical management strategy? b. planning of treatment interventions?; or c. prevention of unneeded diagnostic studies or interventions or preventable exposures?*” is not relevant to whether or not a pacemaker is in place, but rather pertain directly to the MRI examination itself. For instance, if a given MRI examination were deemed important to a clinical management strategy in a patient without a PM/ICD, it would also be important to a clinical management strategy in a patient with an MR compatible PM/ICD. The presence of a PM/ICD does not make a difference as to whether or not an MRI examination is important to a clinical management strategy, so long as the recommended guidelines of the manufacturer for the FDA-approved device are adhered to.

NASCI and ACR also believe that issues of safety of specific devices as in query 2 stating “*Do results of MRI in PM/ICD beneficiaries with implanted cardiac devices affect patient outcomes related to a. survival?, b. quality of life, c. adverse events during and after MRI scanning?*”, are the purview of the Food and Drug Administration. These safety related questions should be addressed and likely were addressed at the time of FDA approval of the device. Any further safety assessment should fall under the auspices of the FDA and not CMS. Furthermore, CMS beneficiaries who have received this FDA-approved device should not be penalized by non-coverage.

NASCI and ACR believe that the FDA's approval of specific implanted pacemakers as safe and effective for use with MRIs should be sufficient as the standard of safety for these devices for CMS to remove the safety contraindication in the current NCD and to not pursue NCD with continuing evidence development.

Patients with FDA-approved devices should have the same access to medically necessary MRIs as patients without implanted cardiac devices. We specifically request that the contraindication language in section 220.2.C.1 of the current policy be replaced with the following,

“The MRI examination is not covered when the following patient-specific contraindications are present: It is not covered for patients with pacemakers that have not been approved by the FDA for use in the MRI environment.”

NASCI and ACR are pleased to review and comment on the proposed NCD and are willing to discuss comments in this letter with Medicare if beneficial. Please feel free to contact us with any questions.



Respectfully Submitted,

Geoffrey D. Rubin, MD

President-elect, North American Society for Cardiovascular Imaging

Harvey L. Neiman, MD, FACR

Chief Executive Officer, American College of Radiology