February 7, 2018

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Centers for Medicare & Medicaid Services
7500 Security Boulevard
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RE: National Coverage Analysis (NCA) for Magnetic Resonance Imaging (MRI) (CAG-00399R4)

The Heart Rhythm Society (HRS), the American College of Cardiology (ACC), Society for Cardiovascular Magnetic Resonance (SCMR), and the American College of Radiology (ACR) are the non-profit professional societies representing most of the practicing clinicians in the United States who care for patients with cardiac rhythm disorders who will benefit from enhanced access to MRI. Our societies are committed to ensuring access to evidence-based patient care.

We appreciate the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) reconsideration of the coverage with evidence development (CED) requirement (section 220.2(C)(1)).

We commend CMS for proposing revisions to the language in section 220.2(C)(1). These modifications generally align with the recent expert consensus statement "HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices".[i]

The organizations appreciate CMS' inclusion of the findings from the MagnaSafe Registry and the previously published findings from the Johns Hopkins Registry, as well as numerous other observational studies demonstrating the safety of performing MRI scans for patients with non-conditional cardiac implantable electronic devices utilizing a 1.5 T magnet. [ii] We recommend that the Agency include in the final policy the recently published article by Nazarian et. al. that includes a significantly larger observational cohort of 1509 patients with either a pacemaker (58%) or implantable cardioverter defibrillator (ICD, 42%). [iii]

The following comments are on conditions for coverage for any MRI for patients with an implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator that does not have FDA labeling specific to use in an MRI environment (Section 3.ii).

In these comments, we make recommendations regarding specific exclusion criteria as well for the requirements for supervision during MRI scanning.

3.ii.a: Less than or equal to 6 weeks since a patient's device implantation or lead revision or surgical modification:

While pacemaker and ICD generators contain ferromagnetic materials, the extent of force and torque is well below the threshold needed to cause movement in a subcutaneous pocket. Patients with devices implanted within six weeks have been included in published studies. The studies that excluded such patients, did so to avoid confounding of lead parameter measurement bias due to spontaneous lead dislodgements or lead-tissue interface maturation that are known to occur in the sub-acute post-operative period. It is not warranted to apply a 6-week waiting period as an MRI does not increase the risk of lead dislodgement and published evidence has not shown any adverse effects in such patients.

We propose that the requirement "It has been ≥ 6 weeks since a patient's device implantation or any lead revision or surgical modification" (3.ii.a.) be removed from the coverage policy.

3.ii.a: ***MRI field strength is ≤ 1.5 Tesla;*** *normal operating mode*

MRI in imaging patients with CIEDs has usually been performed at 1.5T field strengths using the Normal Operating Mode of the scanner. This mode restricts the MR technologist from exceeding vendor-determined specific absorption rate (SAR) limits for that scanner, limiting excessive energy deposition with potential to either injure the patient or harm a device.

We recommend adding "normal operating mode" language to section 3.ii.a to help clarify the energy deposition and avoid excessive levels.

3.ii.b: Pacemaker-dependent patients

The draft policy excludes from the covered indications patients who are pacemaker dependent. However, pacemaker dependent patients are well-represented in published cohorts. In the MagnaSafe registry, there were 284 patients who were pacemaker dependent. In the recently published observational cohort by Nazarian et al., there were 137 patients who were pacing dependent, including 22 patients with an ICD. Pacemaker dependent patients with either a pacemaker or an ICD were also included in other published studies.[iv,v]

As demonstrated by the clinical evidence, we recommend that the requirement "the patient is not pacemaker-dependent" (3.ii.b) be removed from the policy.

3.ii.c: The CIED has no fractured, epicardial, or abandoned leads

Research is underway on MRI for patients with an implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator systems with fractured, epicardial, or abandoned leads. This ongoing study conducted by Nazarian and Halperin suggests no evidence of patient harm. So far, no patients have experienced pain, arrhythmia, or other complications in this setting. Additional evidence of safety in this population was recently published by a group from the Mayo Clinic that reported findings for 80 patients with abandoned leads with no adverse events and no evidence for myocardial injury based upon measurements of troponin values.[vi] The evidence is promising to suggest overall safety of MRI even in the presence of fractured, epicardial, or abandoned leads as long as a safety protocol is followed.

Until further evidence is available and to ensure continued coverage for patients with abandoned, fractured, or epicardial leads in clinical trials, the societies recommend that CMS revise the NCD to include the language in bold. When evidence regarding the safety of MRIs for patients with fractured, epicardial or abandoned leads is more robust, the Societies will seek the opportunity to share the findings with the Agency.

"The implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator system has no fractured, epicardial, or abandoned leads**, unless scans are performed with appropriate consent and/or restrictions for an investigational protocol or registry."**

3.ii.e: Facility Check List: Direct Supervision Criteria

The societies recommend that CMS include in section 3.ii.e the definition of "direct supervision" so electrophysiology providers who are unfamiliar with imaging supervision standards can readily understand the term. This will help clarify expectations, avoid confusion and reduce obstacles to this important diagnostic modality.

A qualified physician, nurse practitioner or physician assistant with expertise with implanted pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy pacemakers, or cardiac resynchronization therapy defibrillators must directly supervise the pre-scan interrogation of the device, monitoring the patient's heart rhythm during the scan, and reprogramming the device and checking to ensure unchanged device function after the scan. Just as the radiology imaging professional must directly supervise the safe acquisition of the MRI imaging data using an appropriate protocol and its interpretation under diagnostic testing rules in 42 CFR § 410.32(b)(3)(ii), the same concepts would apply to the EP professional. In the facility setting, this requires the practitioner be present on the same campus where the services are being furnished. Some

facilities have trained EP technologists or nurses who can monitor the patient during the scan. If that is the case, those technologists or nurses must function within their scope of practice and be directly supervised by the qualified physician, nurse practitioner or physician assistant with expertise with implanted cardiac devices. In the office setting direct supervision requires the practitioner be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.

The societies appreciate CMS's actions to ensure that Medicare coverage supports evidenced- based medical advances in care, ultimately improving access to health care services for patients with these devices. We would welcome the opportunity to discuss these recommendations with the CMS Coverage Analysis Group. If you have questions about the societies' recommendations, please contact Laura Blum at lblum@hrsonline.org.

Sincerely,

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William T. Thorwarth, Jr., MD, FACR
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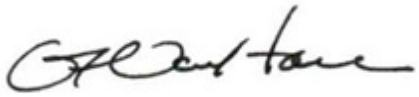

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[i] Indik JH, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm 2017; Jul;14(7):e97-e153.

[ii] Russo RJ, et al. Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator. N Engl J Med 2017;376:755-64.

[iii] Nazarian S, Hansford R, Rahsepar AA, Weltin V, McVeigh D, et al. Safety of magnetic resonance imaging in patients with cardiac devices. N Engl J Med 2017; 377:2555-64.

[iv] Gimbel JR, Bailey SM, Tchou PJ, et al. Strategies for the safe magnetic resonance imaging of pacemaker-dependent patients. Pacing Clin Electrophysiol 2005;28(10):1041–1046.

[v] Cohen JD, Costa HS, Russo RJ. Determining the risks of magnetic resonance imaging at 1.5 tesla for patients with pacemakers and implantable cardioverter defibrillators. Am J Cardiol 2012;110(11):1631–1636.

[vi] Padmanabhan D, Kella DK, Mehta R, et al. Safety of magnetic resonance imaging in patients with legacy pacemakers and defibrillators and abandoned leads. Heart Rhythm 2017; In Press.