



AMERICAN
COLLEGE *of*
CARDIOLOGY



August 10, 2017

Ms. Tamara Syrek-Jensen
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21224

RE: National Coverage Analysis (NCA) Magnetic Resonance Imaging (MRI) (CAG-00399R4)

Dear Ms. Syrek-Jensen:

The American College of Cardiology (ACC) and the Society for Cardiovascular Magnetic Resonance (SCMR) appreciate this opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) as it begins its analysis of MRI coverage. The societies represent the majority of physicians engaged in cardiovascular MRI, as well as those who implant and manage arrhythmia devices in patients. The societies lead in the formation of health policy, standards and guidelines, provide professional medical education, disseminate cardiovascular research and bestow credentials upon cardiovascular specialists who meet stringent qualifications.

Scope of Comments

In the comment development process, we and other stakeholders had questions regarding the lack of detail in the issue summary language posted by CMS in the NCA Tracking Sheet. CMS's intent was not clear, due to the conflicting statements contained in the issue summary regarding noncoverage of patients with implanted cardiac pacemakers, followed by a statement that the "reconsideration is limited to MRI and does not include any coverage determination about magnetic resonance (MR) conditional pacemakers, MR conditional ICDs, or any other pacemaker or ICD." The following comments address both general MRI coverage and MRI coverage for patients with implantable cardiac devices in the event CMS is focusing on one or the other, or both, aspects.

Cardiovascular Indications for MRI

The general clinical utility of MRI is proven for diagnosis of many conditions. While not a comprehensive review, we highlight here the value of MRI for certain cardiovascular indications with which cardiologists are most familiar. Consistent with current guidelines (attached), cardiologists and radiologists utilize cardiovascular MR (CMR) for many cardiac indications.¹ This specifically includes myocardial diseases such as cardiomyopathies, myocarditis,

myocardial iron overload, amyloidosis, and other infiltrative diseases. Cardiac MRI is useful for diagnosis of cardiomyopathy etiology,² and evaluation of myocardial viability prior to revascularization procedures³. Patients with progressive cardiomyopathy, particularly due to inflammatory⁴ or infiltrative⁵ processes require surveillance cardiac MRI examinations to examine response to treatment. The unique value of CMR in patients with heart failure is widely acknowledged.⁶ Its prognostic impact and impact on clinical decision-making has been repeatedly demonstrated.⁷ Moreover, CMR has emerged as a powerful imaging modality in coronary artery disease.⁸ It is considered the gold standard for the in vivo detection and quantitative assessment of myocardial infarction and several studies have shown that first-pass perfusion CMR is at least equivalent to other modalities, specifically nuclear techniques.^{9,10,11} Evidence exists that CMR can provide very important information in patients with valvular disease,^{12,13,14,15,16} myocarditis,¹⁷ and congenital heart disease.¹⁸ Additionally, cardiac electrophysiology procedures that depend upon the identification of abnormal myocardial substrate are increasingly dependent upon cardiac MRI.^{19,20,21,22,23} In this setting, where most patients have implanted non-conditional defibrillators, exclusion of patients with non-conditional devices may adversely affect patient care. Overall, CMR is widely accepted and cardiologists consider its contributions crucial.²⁴ The value added to diagnostic decision-making and subsequent improvement of care delivery result in cost savings to health care providers and payers.^{25 26} It is therefore important that cardiac patients continue to have access to CMR.

MRI of Patients with Implantable Cardiac Devices

CMS considered the use of MRI on patients who have implantable cardiac devices in 2011. At that time, CMS determined that use of MRI is reasonable and necessary for “Medicare beneficiaries with implanted permanent pacemakers when the pacemakers are used according to the FDA-approved labeling for use in an MRI environment.” During that reconsideration, CMS expanded coverage for MRI in patients with a nonconditional device, stating MRI examination “will be covered by Medicare when studied in a clinical study under § 1862(a)(1)(E) (consistent with § 1142 of the Act) if the study meets the criteria” included in the Decision Memo for Magnetic Resonance Imaging (MRI) (CAG-00399R2). Since that time, the field completed additional research in this space that CMS should consider as it undertakes this reconsideration. Several studies, the largest of these being the Magnasafe study (attached), a CMS approved registry published in 2017, demonstrated no adverse events in patients with nonconditional CIEDs undergoing MRI when appropriate protocols were utilized.

Following early results of Magnasafe as well as other smaller studies, stakeholder groups worked together on a document spearheaded by the Heart Rhythm Society and endorsed by the ACC and other organizations that offers expert consensus recommendations upon which physicians can rely as they care for patients with cardiac implantable electronic devices who would benefit from MRI, computed tomography (CT), and/or radiation treatment. These practical recommendations offer providers a framework for evaluating risks and benefits as patients consider treatment options as well as protocols for safe performance of MRI in patients with CIEDs. The *2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices* is attached for your consideration. We encourage CMS to rely upon this document to find a coverage framework that allows physicians and their patients to have a conversation to evaluate the risks and benefits of imaging

options and decide the best path forward for that patient without worry that their imaging may not be covered because of the patient's implantable device.

Thank you for your consideration of these suggestions as you begin the coverage reconsideration process. Please contact James Vavricek, Associate Director for Regulatory Affairs, at jvavricek@acc.org or 202-375-6421 if you have questions or require additional information.

Sincerely,



Mary Norine Walsh, MD, FACC
ACC President



Matthias G. Friedrich, MD, FESC, FACC
SCMR President

Attachments

¹ Knobelsdorff-Brenkenhoff von F, Schulz-Menger J. Role of cardiovascular magnetic resonance in the guidelines of the European Society of Cardiology. *J Cardiovasc Magn Reson*. 2016; 18:1–18.

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⁶ Garbi M, et al. EACVI appropriateness criteria for the use of cardiovascular imaging in heart failure derived from European National Imaging Societies voting. *European Heart Journal Cardiovascular Imaging*. 2016; 17:711–721.

⁷ Pontone G, et al. Prognostic Benefit of Cardiac Magnetic Resonance Over Transthoracic Echocardiography for the Assessment of Ischemic and Nonischemic Dilated Cardiomyopathy Patients Referred for the Evaluation of Primary Prevention Implantable Cardioverter-Defibrillator Therapy. *Circ Cardiovasc Imaging*. 2016;9:e004956.

⁸ Dastidar AG, Rodrigues JCL, Baritussio A, Bucciarelli-Ducci C. MRI in the assessment of ischaemic heart disease. *Heart*. 2016; 102:239–252.

⁹ Greenwood JP, et al. Cardiovascular magnetic resonance and single-photon emission computed tomography for diagnosis of coronary heart disease (CE-MARC): a prospective trial. *Lancet*. 2012; 379:453–460.

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¹¹ Greenwood JP, Herzog, BH, Brown JM, Everett CC, Nixon J, Bijsterveld P, Maredia N, Motwani M, Dickinson CJ, Ball SG, Plein S. Prognostic Value of Cardiovascular Magnetic Resonance and Single-Photon Emission Computed Tomography in Suspected Coronary Heart Disease: Long-Term Follow-up of a Prospective, Diagnostic Accuracy Cohort Study *Ann Intern Med*. 2016;165(1):1-9

¹² Harris AW, et al. Cardiac Magnetic Resonance Imaging Versus Transthoracic Echocardiography for Prediction of Outcomes in Chronic Aortic or Mitral Regurgitation. *Am J Cardiol*. 2017; 119:1074–1081.

¹³ Myerson SG, d'Arcy J, Christiansen JP, Dobson LE, Mohiaddin R, Francis JM, Prendergast B, Greenwood JP, Karamitsos TD, Neubauer S. Determination of Clinical Outcome in Mitral Regurgitation with Cardiovascular Magnetic Resonance Quantification CLINICAL PERSPECTIVE. *Circulation*. 2016; 133:2287–2296.

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- ¹⁵ Chambers JB, et al. Appropriateness criteria for the use of cardiovascular imaging in heart valve disease in adults: a European Association of Cardiovascular Imaging report of literature review and current practice. *European Heart Journal Cardiovascular Imaging*. 2017; 18:489–498.
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- ²² Priori SG, Wilde AA, Horie M, et al. HRS/EHRA/APHRS Expert Consensus Statement on the Diagnosis and Management of Patients with Inherited Primary Arrhythmia Syndromes. *Heart Rhythm*, February 2014 Volume 30, Issue 1, Pages 1–28.
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