



August 1, 2017

Ms. Tamara Syrek-Jensen
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

The Heart Rhythm Society (HRS) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) request for comment on this national coverage analysis to reconsider coverage indications in the national coverage determination (NCD) for Magnetic Resonance Imaging (MRI)(CAG-00399R4). Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals. Its members include 6,100 physicians, scientists, nurses and other allied health professionals in more than 90 countries who specialize in electrophysiology and perform basic, clinical, and translational research science. Electrophysiology is a distinct subspecialty of cardiology, and adult electrophysiologists are board certified through the American Board of Internal Medicine.

Since CMS updated the NCD to cover MRI under the Coverage with Evidence Development (CED) for cardiovascular implantable electronic devices (CIEDs) in February 2011, research in the field of MRI and CIEDs rapidly has been evolving. Due to these developments, the HRS along with other collaborators, developed a consensus statement titled "HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices" located at <http://www.hrsonline.org/Policy-Payment/Clinical-Guidelines-Documents/2017-HRS-Expert-Consensus-Statement-on-Magnetic-Resonance-Imaging-and-Radiation-Exposure-in-Patients-with-Cardiovascular-Implantable-Electronic-Devices>. This consensus statement was intended to help cardiologists, radiologists, radiation oncologists, and other health care professionals involved in the care of adult and pediatric patients with cardiac implantable electronic devices (CIEDs) who are to undergo magnetic resonance imaging (MRI), computed tomography, and/or radiation treatment. The document also addresses the safety of employees with CIEDs who might come into an MRI environment.

Eleven societies collaborated on this Expert Consensus Statement, including the American College of Cardiology (ACC), American College of Radiology (ACR), American Heart Association (AHA), Asia Pacific Heart Rhythm Society (APHRs), American Society for Radiation Oncology (ASTRO), Council of Affiliated Regional Radiation Oncology Societies (CARROS), European Heart Rhythm Association (EHRA), Japanese Heart Rhythm Society (JHRS), Pediatric and Congenital Electrophysiology Society (PACES), Sociedade Brasileira de Arritmias Cardíacas (SOBRAC), and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLAECE).

While HRS appreciates that CMS updated the MRI NCD in July 2011 to remove the contraindication for Medicare coverage of MRI in beneficiaries with implanted pacemakers (PMs) when the PMs are used according to the FDA-approved labeling for use in an MRI environment, we recommend that CMS:

- Further update the NCD for MRI to acknowledge this consensus statement; and,

- Further revise the NCD to provide for patients with an MR non-conditional CIED system to undergo MR imaging under certain circumstances when the MRI is the best test for the patient's condition and aligns with the criteria as specified in the recently published expert consensus statement.

Because of its unique capabilities, MRI has become a critical tool for evaluating patients with a variety of diseases or conditions. HRS appreciates CMS's actions to ensure that Medicare coverage supports advances in care, ultimately providing access to health care services for patients with these devices.

Should you have additional questions, please contact Laura Blum, HRS's Vice President of Health Policy at (202) 464-3489.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Van Hare". The signature is fluid and cursive, with a large initial "G" and a long, sweeping underline.

George F. Van Hare, MD, FHRS, CCDS, CEPS-PC
President, Heart Rhythm Society