



SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE

President

ANDREW POWELL

Boston, MA, USA

andrew.powell@cardio.chboston.org

Vice President

JAMES CARR

Chicago, IL, USA

jcarr@northwestern.edu

Secretary-Treasurer

SUBHA RAMAN

Columbus, Ohio, USA

raman.1@osu.edu

Vice Secretary-Treasurer

SVEN PLEIN

Leeds, UK

s.plein@leeds.ac.uk

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Lausanne, Switzerland

mstuber.mri@gmail.com

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Auckland, New Zealand

Chief Executive Officer

CHIARA BUCCIARELLI-DUCCI

c.bucciarelli-ducci@scmr.org

September 27, 2019

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1717-P
P.O. Box 8013,
Baltimore, MD 21244-1850

RE: [CMS-1717-P] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

Comments submitted electronically via www.regulations.gov

Dear Administrator Verma:

The Society for Cardiovascular Magnetic Resonance (SCMR) appreciates the opportunity to comment on the proposed Hospital Outpatient Prospective Payment System rule for 2020. SCMR is the international professional society representing physicians, scientists, technologists and nurses advocating for research, education and clinical excellence in the use of cardiovascular magnetic resonance (CMR).

Clinical Homogeneity

Under the proposed Hospital Outpatient Prospective Payment System (OPPS) rulemaking for 2020, CMS again includes medical services in the imaging Ambulatory Payment Classification (APC) groups with little regard for clinical homogeneity between services or recognition of differences in resource use. As the Agency is aware, the law states: SSA 1833(t)(2)(B) "the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates."

Prior to the consolidation of the imaging APCs from 17 to 7, CPT 75563 (cardiac magnetic resonance for morphology and function with contrast, with stress) was grouped with clinically comparable services (nuclear cardiology stress perfusion codes) in former APC 0377 (2015) and then APC 5593 (Level 3 Nuclear Medicine and Related Services) (2016). Many of the services in this APC are aimed at investigating the heart and are nearly identical clinically, both in the work entailed and in function. Having **removed CPT 75563** (cardiac magnetic resonance for morphology and function with contrast, with stress) **from APC 5593** (Level 3 Nuclear Medicine and Related Services) (2016) **contradicts the principle of clinical homogeneity that CMS is charged to implement.**

For example, the **clinical labor and resources needed to perform cardiac MRI rest/stress perfusion (CPT 75563) are nearly identical to myocardial perfusion imaging SPECT CPT code 78542**, with the exception that the imaging is performed with an MRI scanner rather than a SPECT camera. Different perfusion agents are required: Gadolinium for MRI and radionuclides for SPECT. Both procedures use the same drugs to produce vasodilation. Staff resources are similar requiring a technologist, nurse and supervising/interpreting physician. The total stress and image acquisition time is also about the same for both procedures being on the order of 45 minutes. It should be noted that overall costs to operate an MRI are much higher than for a SPECT camera. Initial capital costs for a cardiac-equipped **MRI system is \$1.5 million vs. \$350,000 for SPECT**. A yearly **maintenance contract for MRI is \$125,000 vs. \$40,000 for a SPECT camera**. We understand **this difference is not supported by the cost data used by CMS to determine OPPS rate-setting**. We suspect this may be due to the CMS MRI cost center policy which requires cardiovascular magnetic resonance services to be assigned to the MRI cost center. In actuality, **cardiovascular magnetic resonance services may be better aligned to the Cardiology cost center**, where echocardiography is assigned.

Importantly, the **clinical indications for stress cardiac MRI and SPECT myocardial perfusion imaging SPECT are identical**, i.e. both tests are indicated in patients with cardiac angina with known or suspected coronary artery disease. Moreover, the information that both tests can provide is the same, i.e. they can detect the extent and amount of myocardial ischemia which can guide clinicians towards either coronary intervention or medical treatment. These principles are confirmed by clinical practice guidelines of leading cardiology societies.

In 2015 and 2016, CMS accepted SCMR's arguments that CPT 75563 is clinically similar to nuclear cardiology stress perfusion codes. However, in 2017, CMS opted to move CPT 75563 to APC 5573. This APC includes a number of diagnostic services with which CPT 75563 has little in common clinically, such as MRI of the spine or pelvis. MRI exams of static body parts typically require only a single MRI technologist to perform and can be completed in 20 – 30 minutes. It is important to note that Cardiovascular MRI exams typically take around 45 minutes to perform, and stress Cardiovascular MRI exams require additional personnel to administer stress agents and monitor the patient, in a very similar fashion as for a myocardial perfusion imaging SPECT. Literally thousands of images are generated in a typical Cardiovascular MRI exam, covering multiple slices, orientations, and temporal phases of dynamic physiological processes such as perfusion, cardiac function, and blood flow. Evaluation of static structures such as the spine and pelvis requires far fewer images. **Cardiovascular MRI requires intensive post-processing** to extract quantitative information and generate the Cardiovascular MRI report, that **neither spine nor pelvis MRIs require**.

Additionally, Cardiovascular MRI also requires a high level of safety monitoring including advanced levels of nursing monitoring and constant communication with the patient during stress is necessary to assess symptoms. Given that Cardiovascular MRI is offered to patients with cardiovascular diseases, the entire clinical

staff must be prepared to deal with **potential cardiovascular emergencies** including heart block, severe bradycardia, excessive tachycardia, hypotension, or severe ischemic symptoms such chest pain and shortness of breath, or even cardiac arrest. **None of this additional effort and expertise is comparable to the other diagnostic services in APC 5573.**

The Society for Cardiovascular Magnetic Resonance also is concerned that CPT 75561 (cardiac magnetic resonance imaging for structure and morphology w/out contrast, followed by contrast, and further sequences) remains in APC 5572, a group with services that are not clinically similar or similar in resource use. For example, CPT 75561 has little in common with CT of the abdomen or pelvis or MRI of the neck and spine. CPT 75561 is more comparable to services in APC 5573 (Level 3 Imaging with Contrast).

We respectfully request the Agency to address, in the final rule, how it determines which services are clinically similar. We observe that CMS has constructed many APCs with a mix of imaging services that are dissimilar and yet preserves the clinical homogeneity of some APCs, such as nuclear medicine services.

Payment Disruptions

As noted in the chart below, the cardiovascular MRI codes, especially CPT 75561 and CPT 75563, have seen significant reductions in the APC payment for these services. These are the most commonly performed Cardiovascular MRI services. Sustained underpayment relative to cost is disruptive and cannot be easily absorbed by cardiology and radiology departments that provide these procedures. Hospitals will not continue to offer Cardiovascular MRI services when the payments continue to fall significantly below costs.

CPT Code	2015 APC Payment	2016 APC Payment	2017 APC Payment	2018 APC Payment	2019 APC Payment	2020 Proposed APC Payment
75557 Cardiac MR imaging for struct and morph w/o contrast	\$286.30 APC 0336	\$273.54 APC 5581	\$225.81 APC 5523	\$245.22 APC 5523	\$230.56 APC 5523	\$231.28 APC 5523
75559 Cardiac MR imaging for struct and morph w/o contrast w/stress imaging	\$286.30 APC 0336	\$441.36 APC 5592	\$225.81 APC 5523	\$245.22 APC 5523	\$497.49 APC 5524	\$474.44 APC 5524

75561 CMR morphology and function w contrast	\$482.89 APC 0337	\$454.32 APC 5582	\$426.34 APC 5572	\$456.34 APC 5572	\$385.88 APC 5572	\$373.45 APC 5572
75563 CMR morphology and function w contrast, w stress	\$1,140.10 APC 0377	\$1,108.46 APC 5593	\$656.63 APC 5573	\$681.83 APC 5573	\$691.75 APC 5573	\$682.96 APC 5573

The Society for Cardiovascular Magnetic Resonance requests that CMS consider how it might appropriately define and place “low volume” services within a modified APC structure that would support fair and appropriate reimbursement for low volume services. We know that higher volume services drive the payment weights for the APCs. Given this, the APC structure has the unintended effect of hampering the integration of beneficial technology, such as cardiovascular magnetic resonance, into more widespread clinical practice. We request that the Agency brings together numerous stakeholders to examine the variables that result in seemingly artificially low payment for some services, particularly lower volume services such as CPT 75561 and CPT 75563. Such a comprehensive analysis cannot be undertaken within the confines of a 60-day comment period.

Additionally, the **Society for Cardiovascular Magnetic Resonance requests that CMS consider moving CPT 75563 back to APC 5593.** An analysis completed for the Society for Cardiovascular Magnetic Resonance by its consultant suggests this would have no effect on the reimbursement rate for APC 5593. We further request that CMS move CPT 75561 to APC 5573, noting it would require a waiver of the 2x rule.

Use of CT and MRI Cost Centers

We believe another factor resulting in **inadequate payment levels is the Cost to Charge (CCR)** methodology for MRI services. We urge the Agency to halt use of the standard MRI and CT cost centers.

Based on extensive modeling and data supplied by the American College of Radiology (ACR), the **CCRs for CT and MR cost centers are inaccurate**, too low, and are depressing the valuation of APCs that include CT and MR, often resulting in advanced and non-advanced imaging being paid at the same level. The data show that there is something fundamentally flawed with the MRI and CT cost center data.

According to the ACR, the CCRs for selected CT and MRI procedures show a significant number of CCRs that are close to zero. These near zero CCRs indicate that even when hospitals create standard cost centers, they are likely unable to accurately re-allocate many costs that are already allocated across hospital departments to new CT and MR departmental cost centers. For these hospitals, the CCRs probably reflect allocations of staffing and dedicated departmental expenses, while the costs of equipment, some costs associated with space (e.g., lead in walls), and other administrative costs have been spread across all hospital departments and have not been moved. Per ACR’s analysis, the presence of these near **zero CCRs will contribute to underestimated costs** used in rate setting, pulling rates for CT and MRI procedures down below their actual cost and further eroding payment accuracy.

We note that other imaging modalities, such as echocardiography, are not treated in this manner. Hospitals have standard accounting practices for high cost moveable equipment and it is inconsistent and burdensome to expect hospitals to account CT and MRI in a different manner than they deal with other types of equipment.

In conclusion, **CMS' current structure of the imaging APCs has demonstrated significant variation** in the grouping of services and resulted in services that are not clinically similar or similar in resource use being grouped together. It is difficult to understand CMS' methodology and underlying intent with placement of codes in the APC structure. Fundamentally, **the OPSS methodology appears to foster inequities in patient access to modern medicine**, including diagnostic imaging techniques, such as cardiovascular MRI, that have an appropriate place in the spectrum of patient care. It is a cause of concern that **inaccurate administrative processes hinder potentially life-saving diagnostic opportunities** for both patients and physicians. The effects of this translates in **inequalities to access to care**, which is particularly relevant in comparison to Europe: cardiovascular diseases and patients are the same, yet **American patients are significantly disadvantaged** compared to Europeans when it comes to access to modern diagnostic cardiology, not for lack of technology or skills but for an inaccurate payment system. With inappropriate APC placement and artificially low reimbursement levels, patient access to these newer technologies is compromised.

The Society for Cardiovascular Magnetic Resonance wishes to warmly thank the Centers for Medicare and Medicaid Services for their continued commitment to improve patients' health and wellbeing by promoting an adequate payment system that does not hinder adequate patient management. We appreciate this is an incredibly complex and very challenging task, but we hope you will find our observations helpful in considering, and resolving, some of the issues highlighted.

Please contact Chiara Bucciarelli-Ducci, MD, PhD, CEO of the Society for Cardiovascular Magnetic Resonance, if you have questions or require additional information.

Thank you for your consideration.

Sincerely,



Chiara Bucciarelli-Ducci, MD, PhD, FESC, FRCP
Chief Executive Officer
Society for Cardiovascular Magnetic Resonance
Email: c.bucciarelli-ducci@scmr.org



Andrew J. Powell, MD
President
Society for Cardiovascular Magnetic Resonance