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CARDIOLOGY



NASCI
North American Society for Cardiovascular Imaging



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Centers for Medicare and Medicaid Services
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RE: CAG 00399R (NCA Tracking Sheet for Magnetic Resonance Imaging)

On behalf of the American College of Cardiology (ACC), American College of Radiology (ACR), North American Society for Cardiovascular Imaging (NASCI) and the Society for Cardiovascular Magnetic Resonance (SCMR), we thank you for granting our request to open a reconsideration of the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) (220.2).

Although we have previously submitted extensive comments on this issue, we very much appreciate the opportunity to respond to the Agency's request for comments on CAG 00399R. To reiterate, we specifically request that blood flow measurement be removed from the list of non-covered indications as listed in 220.2, so that Medicare carriers are permitted to use carrier discretion to cover cardiac magnetic resonance imaging for morphology and function with flow/velocity quantification.

Non-coverage of MRI flow quantification leads to additional testing that is often more costly, inconvenient, less comfortable for the patient, and carries greater risk if a patient is forced to undergo invasive angiography with its resultant radiation and contrast exposure. Furthermore, there is ample evidence in the literature and ample clinical experience to support the view that MRI flow quantification is more reliable and reproducible and leads to better treatment decisions than alternative diagnostic techniques.

Flow quantification has been accepted in clinical practice for at least the last 20 years. Treating physicians provide this service to make downstream decisions for patients based on 1) the result of the flow velocity determinations, 2) its proven ability to perform at the level of the "gold standards" in accuracy, and 3) the demonstrations that flow can obtain data noninvasively when other modalities cannot.

NCD Manual Section 220.2



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Section 220.2 of the National Coverage Determination (NCD) Manual, effective since 1985, establishes coverage of MRI for a number of uses. Non-coverage of blood flow measurement has been included in the NCD for MRI since 1985. Our organizations have discussed this issue with CMS on a number of occasions and through regulatory rulemaking processes. We again ask CMS to reconsider Section 220.2 and specifically remove the reference to blood flow measurement in the nationally non-covered indications. Agency staff in the Coverage and Analysis Group have stated on two occasions (April 2008 and June 2008) that removing “blood flow measurement” from the list of nationally non-covered indications would remove obstacles to coverage of cardiac MRI. Once deleted, the last paragraph of the NCD would permit local contractor discretion for the coverage of cardiac magnetic resonance imaging for morphology and function with flow/velocity quantification. This last paragraph states: “All other uses of MRI for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local contractor discretion.

NCD Manual Section 220.3

The Agency has asked whether imaging of the cardiac chambers and cardiac function is non-covered as a result of Section 220.3. Again, we note that flow/velocity measurements made via phase-contrast imaging have little in common with the phase contrast technique that was used in the past to create older anatomic magnetic resonance angiography images. Instead it is a technique that generates quantitative data about flow and velocity, and as currently applied is not used to demonstrate anatomic detail. The flow/velocity information obtained via cardiac MRI is functional in nature. It is the only technique that can directly measure flow without making assumptions of vessel diameters, thus a more advanced and physiological technique than the standard echocardiography.

Conflicts between NCD Manual Sections 220.2 and 220.3

Non-coverage of blood flow measurement for MRI is in direct conflict with the NCD for Magnetic Resonance Angiography (MRA) in section 220.3 of the NCD Manual (originally published as section 50-14 of the Coverage Issues Manual) and remains a source of confusion for providers and Medicare contractors. As stated by CMS in the NCD, “MRA is a non-invasive diagnostic test that is an application of magnetic resonance imaging (MRI). By analyzing the amount of energy released from tissues exposed to a strong magnetic field, MRA provides images of normal and diseased blood vessels as well as visualization and *quantification of blood flow* through these vessels” [emphasis added]. We believe that the reference to non-coverage of blood flow measurement in the NCD for MRI was inadvertently retained when the NCD for MRA was released.

Technological Advances and State of the Art Application of CMR



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We reiterate that in 1985, cardiac MRI with flow/velocity quantification had only just been described in the literature. Now, almost a quarter century later, flow quantification and velocity assessment are requisite to any functional cardiac MRI examination when determination of valve function and the extent of valvular insufficiency and stenosis are necessary. Section 220.2 of the NCD Manual dictates that physicians must perform an incomplete cardiac MRI examination and then refer the patient for additional and/or potentially more invasive studies such as transesophageal echocardiography, transthoracic echocardiography or cardiac catheterization in order to determine valve area, extent of regurgitation or gradient, or Qp/Qs ratio.

Moreover, flow quantification is critical in some congenital cardiac MRI examinations to determine the severity of intracardiac shunting (Qp/Qs ratio). These flow measurements are used in much the same way as Doppler measurements are used in echocardiography. The temporal resolution of this methodology is good and the information obtained is accurate. These measurements are widely accepted as being equally accurate to those obtained with echocardiography. Flow quantification measurements are particularly useful when performed as part of a cardiac MRI examination in cases where, if they were not performed at the time of MRI, an additional study would be necessary. Performing these measurements at the time of MRI examination often prevents the need for an additional echocardiogram. Since many patients with mild shunts do not present until later in adulthood, and those with significant shunts and their sequelae have long term disability, phase contrast quantification of flow is increasingly important to the Medicare beneficiary population.

In the case of the need for a Qp:Qs (pulmonic to systemic flow) ratio, the MRI examination can save the patient from an additional invasive catheterization. Flow quantification by MRI also is useful in cases where echocardiographic imaging is suboptimal (e.g., in patients with prior chest wall surgery or unusual body habitus). Additionally, MRI flow quantification is the principal noninvasive method for the assessment of the pulmonic valve which, because of its close proximity to the chest wall, is poorly evaluated by echocardiography.

An argument that these measurements remain investigational is inconsistent with current literature and widespread clinical acceptance. Studies published as early as 1995 have demonstrated the accuracy of MRI determinations of valve disease³³ and Qp/Qs ratios³⁴ compared with both invasive and other non-invasive methods. Functional evaluation of cardiac valves with MRI in most instances is equal in accuracy to echocardiography. To require that Medicare beneficiaries undergo an additional and potentially more invasive examination (e.g., echocardiography or catheterization) following cardiac MRI to assess valvular stenosis or regurgitation based on an outdated coverage policy is inappropriate and, ultimately, not cost effective.



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Thank you again for your consideration of our request to remove the reference to blood flow measurement from the list of non-covered indications in the NCD for MRI.

If you have any questions or need additional information, please contact either Denise Garris by phone at 202-527-1069 or by email at denise@korrisgroup.com; Gretchen Wyatt by phone at 202-375-6392 or by email at gwyatt@acc.org or Anita McGlothlin by phone at 703-648-8900, ext. 4923 or by e-mail at amcglathlin@acr.org.

Sincerely,

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