December 24, 2008

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Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

**Re: <u>Formal Request for Reconsideration of the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) to Remove Reference to Blood Flow Measurement (section 220.2 of the Medicare NCD Manual)</u>**

Dear Dr. Phurrough:

On behalf of the American College of Radiology (ACR), the American College of Cardiology (ACC), North American Society for Cardiovascular Imaging (NASCI), and the Society for Cardiovascular Magnetic Resonance (SCMR), we formally request a reconsideration of the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) to permit local contractor discretion for the coverage of cardiac magnetic resonance imaging for morphology and function with flow/velocity quantification. Specifically, we request removal of the reference to blood flow measurement in the following paragraph of the NCD that describes nationally non-covered indications:

> "The CMS has determined that ***blood flow measurement***, imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered" [emphasis added].

Non-coverage of blood flow measurement has been included in the NCD for MRI since 1985. It 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 a source of considerable confusion for physicians, 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 blood flow measurement in the NCD for MRI was inadvertently retained when the NCD for MRA was released.

We recommend that the reference to blood flow measurement be deleted from the NCD for 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."

**Background**

Non-coverage of blood flow measurement in the NCD for MRI came to our attention when new cardiac MRI codes, created by the CPT® Editorial Panel as a result of technological changes in MRI scanning, were incorporated into Medicare's physician fee schedule and outpatient prospective payment system (OPPS) for CY 2008. The CPT® Editorial Panel created eight new cardiac MRI codes and deleted five existing cardiac MRI codes. The new codes are:

75557 Cardiac magnetic resonance imaging for morphology and function without contrast material;
75558 Cardiac magnetic resonance imaging for morphology and function without contrast material; with flow/velocity quantification
75559 Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging
75560 Cardiac magnetic resonance imaging for morphology and function without contrast material; with flow/velocity quantification and stress
75561 Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences;
75562 Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with flow/velocity quantification
75563 Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging
75564 Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with flow/velocity quantification and stress

The deleted codes are:
75552 Cardiac magnetic resonance imaging for morphology; without contrast material
75553 Cardiac magnetic resonance imaging for morphology; with contrast material
75554 Cardiac magnetic resonance imaging for function, with or without morphology; complete study
75555 Cardiac magnetic resonance imaging for function, with or without morphology; limited study
75556 Cardiac magnetic resonance imaging for velocity flow mapping

The ACR and the ACC surveyed the eight new codes through the established AMA/Specialty Society Relative Value Scale Update Committee (RUC) process and CMS accepted the RUC's recommendations. However, for the four new cardiac MRI codes that contain the phrase "with flow/velocity quantification," CMS stated the following in the Final Rule: "...four of the new codes incorporate blood flow measurement, which remains one of the nationally non-covered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program..." These four codes were assigned status indicator "N" (Non-covered) in Addendum B of the physician fee schedule final rule and status indicator "E" (Non-covered) in Addendum B of the OPPS final rule.

The ACR, ACC, NASCI, and SCMR were surprised and disappointed by the CMS decision to non-cover these four new cardiac MRI codes without prior consultation with us. We recognized that Medicare had not paid for the deleted code 75556 (Cardiac magnetic resonance imaging for velocity flow mapping) for many years; however, there had been considerable confusion regarding the reasons for CMS's decision not to pay for this examination. Even though code 75556 was listed in CPT as a stand-alone code, in clinical practice, it was seldom (if ever) performed as a stand-alone service. Since 75556 was almost always performed in conjunction with other cardiac MRI examinations, we assumed a major part of CMS's decision to not pay for 75556 stemmed from the fact that many of the resources required to provide this service would be included in the base code (75552, 75553 or most commonly 75554). Since CMS had not referenced the NCD for MRI as the basis for nonpayment, it had not been clear to physicians or providers that non-coverage of blood flow measurement in the NCD for MRI was the basis for nonpayment of 75556. In fact, we could find no statements in any CMS transmittal where CMS discusses the reasons why flow/velocity measurements for cardiac imaging are "investigational" or not "reasonable and necessary." Had we realized that the basis for CMS's non-coverage of 75556 was the NCD for MRI, the ACR, ACC, NASCI, and SCMR would have requested reconsideration of the NCD at a much earlier date.

Medicare's own contractors also have been confused by the conflicting statements regarding blood flow in the NCDs for MRI and MRA. Some Medicare contractors have lumped 75556 into MR angiography services and have denied payment for 75556 based on the fact that the NCD for MRA limits coverage to specific indications which do not include determinations of cardiac flow/velocity measurements. For example, one contractor's LCD defines the reason for non-coverage as follows: "Other usages of MRA (72159, 72198, 73225) including cardiac MRI for velocity flow mapping (75556) are considered investigational and are not eligible for reimbursement." Flow/velocity measurements have little in common with magnetic resonance angiography and we strongly believe the existing NCD for MRA is not applicable.

The ACR and ACC are particularly disappointed with CMS's decision to not cover the new cardiac MRI codes with flow/velocity determinations because it was our intent to bring forward a set of bundled codes that accurately described the permutations of performing cardiac MRI without having to use a series of component codes where providers would pick and choose the services

performed. At the urging of CMS, the CPT Editorial Panel and the RUC, specialty societies had been asked to create codes that describe the entire package of care rather than a series of component codes or add-on codes in order to eliminate the possibility of duplication of work and practice expense.

The ACR and the ACC took this advice to heart and created such a set of codes for cardiac MRI. Because the codes that include flow/velocity determinations are the workhorse examinations for cardiac MRI studies, the CMS policy puts radiologists and cardiologists in the unanticipated conundrum of choosing between several suboptimal options. Physicians can do the complete examination, code the complete examination and not be reimbursed. Alternatively, the physician can do the complete examination and down-code the examination to the codes that do not include velocity determinations. However, this method violates CPT coding policy, and places providers at risk of Medicare fraud for coding the incorrect examination for the sole purpose of obtaining reimbursement. While either of these alternatives will do what is correct for the patients, both are untenable for the physicians.

Unfortunately CMS policy, which is based on a 1985 determination that flow velocity determinations by MRI are not reasonable and necessary, now 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. Based on discussions with you and other CMS staff on July 23, 2008, we now understand that the solution to this problem requires a reconsideration of the NCD for MRI.

**Benefit Category**

We believe MRIs (including cardiac MRIs with flow/velocity quantification) are diagnostic tests that fall under section 1861(s)(3) of the Social Security Act (diagnostic tests), section 1861(b)(3) of the Act (inpatient diagnostic services), and section 1861(s)(1) of the Act (physician services).

**Cardiac MRI for Morphology and Function with Flow/Velocity Quantification**

As described above, it had not been made clear to us until recently that the reasons for non-coverage date back to 1985 when blood flow measurement was not considered reasonable and necessary. We note that in 1985 cardiac MRI with flow/velocity quantification had only just been described in the literature. Twenty-three years 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.

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.

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 disease and Qp/Qs ratios' 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.

The ACR, ACC, NASCI, and SCMR strongly believe the existing NCD for MRA is not applicable to cardiac MRI with flow/velocity measurements. The flow/velocity information obtained via cardiac MRI is functional, and although the morphology of valves can be inferred by this functional information, the examination is not used to create an anatomic image and, as such, is not similar to magnetic resonance angiography or MR spectroscopy.

While initial studies focused on comparing flow velocity to accepted gold standards, once flow was determined to be accurate as compared to the standards, clinical practice for some patients changed. For more than 15 years flow has been an accepted clinical practice in the medical community and it is logical that recent studies in cardiac MRI may have not addressed flow.

We believe that accepted clinical practice of flow and the ability of treating physicians to make downstream decisions serve as surrogate evidence of beneficial outcomes 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.

Thank you for your consideration of our request to remove the reference to blood flow measurement in the NCD for MRI. This outdated reference conflicts with the NCD for MRA and

should have been deleted in 1995 when CMS initially covered MRA. This change will permit local contractor discretion for the coverage of cardiac magnetic resonance imaging for morphology and function with flow/velocity quantification, a clinically valuable service that should be eligible for coverage by Medicare. For your reference, we have attached a list of relevant articles from the peer-reviewed medical literature that demonstrate the clinical value of flow/velocity quantification for the assessment of valvular regurgitation, valvular stenosis, intracardiac shunts (Qp:Qs) and cardiac output or index.

If you have any questions or need additional information, please contact Anita McGlothlin by phone at 703-648-8900, ext. 4923 or by e-mail at amcglothlin@acr.org.

Sincerely,

Harvey L. Neiman, MD, FACR
Executive Director, American College of Radiology

W. Douglas Weaver, MD

Douglas Weaver, MD, FACC
President, American College of Cardiology

Pamela Woodard, MD
President, Society for Cardiovascular Magnetic Resonance

Charles Higgins, MD
President, Society for Cardiovascular Magnetic Resonance

Cc: Ken Simon, MD
Ross Brechner, MD

## Attachment: Table of References

| Reference | Valve Assessed/Indication | Sample Size | Reference Standard | Correlation |
|---|---|---|---|---|
| ***Valvular Regurgitation*** | | | | |
| Sondergaard L, et al., 1993[1] | AR, regurgitant fraction | 10 | Angiography; indicator dilution | Angio r = 0.97; Indicator dilution r= 0.82 |
| Honda N, et al., 1993[2] | AR, regurgitant fraction | 26 | Doppler echocardiogram | agreed well; reproducibility r =0.96 |
| Dulce MC, et al., 1992[3] | AR, regurgitant fraction | 10 | Reproducibility | r = 0.99 |
| Gelfand EV, et al., 2006[4] | MR and AR, regurgitant fraction | 177 | Doppler echocardiogram | concordance >95% MR; >100% AR regurgitation grade |
| Hundley WG, et al., 1995[5] | MR, regurgitant fraction | 23 | Angiography | r = 0.96 |
| Kizilbash AM, et al., 1998[6] | MR, regurgitant fraction | 22 | Doppler echocardiogram | r = 0.82 |
| Westenberg JJM, et al., 2005[7] | MR, regurgitant fraction | 10 | Flow at ascending aorta | r = 0.91 |
| Fujita N, et al., 1994[8] | MR, regurgitant fraction | 19 | Doppler echocardiogram | r = 0.87; reproducibility r = 0.99 |
| Rebergen SA, et al., 1993[9] | PR, regurgitant fraction | 18 | RV/LV stroke volumes | r=0.93 |

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| Helbing WA, et al., 1996[10] | PR, duration of regurgitation and peak velocity | 19 | Doppler echocardiogram | r = 0.74-0.82 |
| Li W, et al., 2004[11] | PR, regurgitant fraction | 52 | Doppler echocardiogram | r = -0.82 |
| Ley S, et al., 2007[12] | AR, regurgitant fraction | 32 | Doppler echocardiogram | r = 0.7 |
| Hellgren LL et al., 2008[13] | MR, regurgitant fraction | 18 | Doppler echocardiogram | not comparable (51.6% by MRI vs. 23.3% by echo) |
| Globits S et al., 1990[14] | MR and AR, regurgitant fraction | 46 | Angiography, oximetry | r = 0.91 (AR) and 0.67 (MR) |
| ***Valvular Stenosis*** | | | | |
| Caruthers SD, et al., 2003[15] | AS, gradient | 24 | Doppler echocardiogram | peak r = 0.83; mean r = 0.87 |
| Eichenberger AC, et al., 1993[16] | AS, gradient | 19 | Doppler echocardiogram and angiography | r = 0.96-0.97 |
| Kilner PJ, et al., 1993[17] | AS and MS, gradient | 28 | Doppler echocardiogram | standard deviation of differences 0.49 m/sec |
| Heidenreich PA, et al., 1995[18] | MS, gradient | 16 | Doppler echocardiogram | peak r = 0.82-0.89; mean r = 0.84-0.95 |
| Lin SJ, et al., 2004[19] | MS, gradient and estimation of valve area | 17 | Doppler echocardiogram | r = 0.86 |
| Tanaka K, et al., 2007[20] | AS | 22 | Doppler echocardiogram | r=0.93 |
| Yap SC, et al., 2007[21] | AS | 20 | Doppler echocardiogram | r=0.91 |

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| ***Intracardiac Shunts (Qp:Qs)*** | | | | |
| Esmaeili A, et al., 2006[22] | Qp:Qs ratio | 14 | Angiography, oximetry | r = 0.80 |
| Hundley WG, et al., 1995[23] | Qp:Qs ratio | 21 | Angiography, oximetry | r = 0.94 |
| Beerbaum P, et al., 2001[24] | Qp:Qs ratio | 50 | Angiography, oximetry | mean difference 2% |
| Brenner LD, et al., 1992[25] | Qp:Qs ratio | 11 | Angiography, oximetry | r = 0.91 |
| Petersen SE, et al., 2002[26] | Qp:Qs ratio | 17 | Angiography, oximetry | r=0.91 |
| Rebergen SA, et al., 1996[27] | Qp:QS ratio (ASD) | 12 | tomographic RV/LV stroke volumes vs. pulmonary and aortic flow volume measurement by velocity mapping | r = 0.98 (aortic) and 0.99 (pulmonary); 0.92 (Qp:Qs vs. stroke vol ratios) |
| Festa P et al., 2006[27] | Qp:Qs ratio (partial anamolous pulmonary venous return) | 14 | Angiography, oximetry | r = 0.85 |
| Powell AJ, et al., 2003[28] | Qp:Qs ratio | 20 | Angiography, oximetry | r=0.75 |
| Arheden H, et al., 1999[28] | Qp:Qs ratio | 36 | Radionuclide angiography | mean difference 14%, reproducibility 1% |
| ***Cardiac Output or Index*** | | | | |
| Hundley WG, et al., 1995[29] | Stroke Volume | 23 | Angiography (Ficks and thermodilution) | Agreement 3±9 Fick; -3±11 thermodilution |
| Jeltsch M, et al., 2008[30] | Stroke Volume | 78 | RV/LV stoke volumes | r=0.97 LVSV; r=0.86 RVSV |

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| Abbreviations: AR = aortic valve regurgitation; MR = mitral valve regurgitation; PR = pulmonic valve regurgitation; AS = aortic valve stenosis; MS = mitral valve stenosis; TOF = tetralogy of Fallot | | | | |


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