

Philips Medical Systems

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Joseph Chin, M.D.
JoAnna Baldwin, M.S.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. Chin and Ms. Baldwin:

On behalf of Philips Medical Systems (“Philips”), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) National Coverage Analysis (NCA) on Cardiac Computed Tomography Angiography (CAG-00385N).

Philips Medical Systems operates in four main business areas: Diagnostic Imaging Systems, Clinical Solutions, Healthcare Information and Customer Services. Our product line includes best-in-class technologies in X-ray, ultrasound, magnetic resonance, computed tomography, nuclear medicine, PET, radiation oncology systems, patient monitoring, information management and resuscitation products. With approximately 33,000 employees worldwide and a presence in more than 100 countries around the world, Philips Medical Systems is firmly established as a worldwide leader in many of the markets it serves

Preliminarily, we wish to express concern about the June 13 notice announcing CMS’s interest in opening a National Coverage Assessment (NCA) for CCTA. That notice specifically states:

CMS is concerned that despite the lack of clinical evidence to demonstrate improved patient health outcomes with CTA, the procedure has been rapidly adopted by the clinical community.

(Emphasis added.) Not only does this language suggest a degree of prejudgment of the clinical value of CCTA, we respectfully suggest that it frames the issue improperly.

In our view, it is inappropriate to require that a diagnostic technology, such as CCTA, demonstrate “improved patient health outcomes”—especially for complex diseases, such as Coronary Artery Disease (CAD)—which are difficult to diagnose and manage. In fact, numerous factors contribute to ultimate health outcomes, including most prominently the quality and efficacy of the available therapies available and patient compliance with medication and other instructions provided by health care professionals. It is perhaps for this reason that the Medicare Act does not cover only those diagnostic services that can demonstrate “improved patient health outcomes” but rather those that are “reasonable and necessary” for the diagnosis or treatment of disease or injury.

We respectfully suggest that, to determine whether the “reasonable and necessary” standard is met, the appropriate question is whether CCTA has the potential to facilitate diagnosis of CAD or other





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cardiac conditions with a high degree of sensitivity and specificity, and whether it provides valuable information that may affect clinical decision-making—not whether CCTA can be demonstrated to result in “improved health outcomes”.

We also note that the June 13 notice appears to reflect a reversal of CMS’s prior thinking regarding the need for a NCD for CCTA. As recently as last year, CMS announced that it had no intention of issuing a NCD for CCTA, but would instead allow Medicare contractors discretion concerning whether, and under what conditions, Medicare coverage would be permitted.

While the CCTA Local Coverage Determinations (LCDs) established by the various Medicare carriers differ in some details, they generally concur on the clinical utility of CCTA in the diagnosis of Coronary Artery Disease (CAD). Moreover, the indications for coverage set forth in the current LCDs are generally consistent with the Model LCD for CCTA formulated by the American College of Cardiology (ACC). We do not believe that there is a pressing need to override existing CCTA LCDs, which have been developed on the local level, sometimes with significant input from the local physician community. However, if CMS decides to move forward with the development of a NCD, we hope that the agency will consider using the existing LCDs as potential models for the NCD.

Having said that, we would like to point out that there is one area where the LCDs do not provide a useful precedent: equipment standards. Unfortunately, there is a wide variation in CCTA equipment requirements established by the local carriers that are unrelated to the diagnostic quality of the studies produced. Local contractors have established various and different requirements relating to the number of detectors, gantry speed, and collimation size.

Significantly, the critical equipment-related issue in the clinical efficacy of CTA as a diagnostic tool is temporal resolution-- that is the ability to deliver image detail in the smallest “window” of time. Excellent temporal resolution results from a combination of factors-- not simply the number of detectors or gantry speed. While these variables certainly contribute to the degree of temporal resolution that is achieved, there is no clinical or technical justification for using them in isolation as the predictive variable. As explained in Attachment A, “Considerations in Cardiac CT: Understanding Temporal Resolution and Rotation Speed For Improved Cardiac Imaging, temporal resolution is affected by many factors, including the acquisition and image reconstruction software. In short, despite the distinctions drawn by the carriers among various types of scanners, the mechanics of the scanner itself cannot be used as a reliable proxy for temporal resolution.

In light of the constant evolution of the technology, we believe that virtually any CCTA equipment standard likely would be quickly outdated. For this reason, we urge CMS to refrain from imposing specific equipment requirements in the NCD, beyond any such requirements that are clearly supported in the clinical literature or by expert consensus, as reflected in the statements of relevant professional associations.

In addition, we urge the agency to follow a number of guidelines in formulating the NCD:

- We are aware that CCTA was included in a Technology Assessment conducted last year entitled “Non-invasive imaging for Coronary Artery Disease.” We caution against using this Technology Assessment as the basis for a NCD, since it was intended to be a



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preliminary assessment directed at six specific questions. Moreover, this report is outdated, since there have been numerous articles on CCTA published since it was issued. For example, a study published in JAMA last year confirmed the fact that CTA, using a 16-detector scanner, can play a pivotal role in reducing the number of unnecessary cardiac catheterizations.¹ See also the articles listed at Attachment B, which provides references for a number of recent articles on the specificity, sensitivity, and clinical utility of CCTA. Even more importantly, the experience of clinicians in utilizing CCTA in the treatment of Medicare beneficiaries and other patients has grown substantially over the past several years, further solidifying the role of this new technology in the diagnosis of CAD. This more recent experience of clinicians in utilizing CCTA for patient care was not considered in the 2006 Technology Assessment.

- For the reasons set forth above, we urge CMS to refrain from establishing equipment requirements related solely to the mechanics of the scanner itself, except as endorsed by relevant professional associations, and should consult closely with the Medical Imaging Technology Association (MITA) for technical input if it is determined that further equipment standards are necessary. Care should be taken to ensure that any equipment standards that are adopted do not unfairly discriminate against a particular manufacturer's equipment based on arbitrary standards unrelated to the diagnostic quality of the studies produced.
- We urge CMS to consult closely with the relevant national professional associations, including the American College of Cardiology and the American College of Radiology, in formulating the list of appropriate indications for CCTA.
- In the event that CMS decides that the peer-reviewed published literature is insufficient at this point to support full coverage for CCTA for the diagnosis of CAD, we urge CMS to formulate an appropriate CED to facilitate the gathering of clinical data from practicing cardiologist who utilize this technology for patient care. In this regard, we urge the agency to work closely with existing registries and professional societies to establish a data collection process that minimizes the administrative burden involved for facilities that provide this important service, and that collects the data needed by CMS as cost-efficiently as possible. We would be delighted to work with CMS and other affected groups to formulate the data elements and to facilitate the use of the registry among our customers.
- We strongly urge CMS to instruct Medicare carriers to continue to provide coverage for CCTA based on their own LCDs, pending issuance of any NCD or CED. The authors of the JAMA study referenced above indicate that if CCTA had been implemented into clinical practice for the entire patient population included in the study, invasive coronary angiography could have been avoided in 37% of the study population. This conclusion is reinforced by data obtained by Philips from the CCTA Data Registry for the first quarter of 2007, which indicates that, during that period, the majority of CCTA cases (65%) were substitutions for nuclear perfusion testing as the entry point in the diagnostic imaging system. Thus, the continued use of CCTA pending the issuance of any NCD has the

¹ "Accuracy of 16-Row Multidetector Computed Tomography for the Assessment of Coronary Artery Stenosis", Mario J. Garcia, MD, et. al.; JAMA, July 26, 2006-Vol 296, No.4.



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potential to result in significant continued savings to the Medicare Program. For this reason, coverage for CCTA should continue to be provided on the basis of the existing LCDs, pending the issuance of any NCD.

- While there are a number of accepted clinical indications for CCTA, the field is evolving rapidly, and any NCD established at this time likely will be quickly outdated. Therefore we believe that any NCD established for CCTA should be reviewed at least annually to ensure that Medicare beneficiaries have timely access to CCTA in appropriate cases.

Philips appreciates the opportunity to comment on this important issue, and we offer our further assistance to CMS in the event that the agency does decide to move forward with a CCTA NCD or CED.

Sincerely,

signed

Laurel Sweeney
Senior Director, Reimbursement & Legislative Affairs
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
(978) 659-2972
laurel.sweeney@philips.com