A New Era for Cardiovascular Imaging? Implications of the Revoked National Coverage Decision for CT Angiography on Future Imaging Reimbursement

On December 13, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a proposed national coverage decision (NCD) memorandum for cardiac computed tomographic angiography (CTA) for the diagnosis of coronary artery disease (CAD) that would have drastically reduced coverage for Medicare beneficiaries for CTA. Under this proposal, Medicare coverage for CTA would have been provided only in a small minority of patients and only in the setting of enrollment in an approved research protocol. In its final ruling, released March 12, 2008, CMS reversed its decision and retained the existing coverage policy that gives local Medicare contractors the discretion to reimburse according to their own policy and without a requirement for research participation. Thus CTA will remain reimbursed by Medicare in all 50 states, with the majority of local contractors having similar policies.

The CMS has been reviewing policies regarding CTA coverage for several years, including a health technology assessment by the Agency for Healthcare Research and Quality (AHRQ) in 2006, a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) review also in 2006, and a public comment period in the summer of 2006 when CMS opened a national coverage analysis for CTA. The proposed NCD issued in December 2007 (1) summarized these data and stated that “the evidence is inadequate to conclude that cardiac computed tomographic angiography (CTA) is reasonable and necessary... for the diagnosis of coronary artery disease (CAD).” However, “the agency believes the evidence is promising for two clinical indications and that coverage with evidence development (CED) would be appropriate” (i.e., if a patient were enrolled in a research study) but only for the following indications: 1) symptomatic patients with chronic stable angina at intermediate risk of CAD; or 2) symptomatic patients with unstable angina at a low risk of short-term death and intermediate risk of CAD.

Further, a clinical study seeking Medicare payment for CTA for the diagnosis of CAD would have been required to address 1 or more of the following questions. 1) Does cardiac CTA have the ability to diagnose or exclude coronary artery disease as well as invasive coronary angiography? 2) Does coronary CTA reduce the need for invasive coronary angiography? 3) Does coronary CTA improve health outcomes for patients with acute chest pain who present in the emergency room or other setting?

Finally, a study must meet a variety of specific standards, which include that the principal purpose of the research study is to test whether the intervention potentially improves the participants’ health outcomes. All other uses of cardiac CTA for the diagnosis of CAD would not be covered, including the screening of asymptomatic patients for CAD.
Cardiac CTA for uses other than the diagnosis of CAD remains at the local contractor’s discretion.

Although this draft policy was abandoned by CMS on March 12, 2008, after consideration of public comments including numerous responses from societies, physicians, industry, coalitions, Congress, and other interested parties (2), this would have been the first time that a diagnostic test would be required to provide evidence on impact on health outcomes rather than simply demonstrate a high level of test performance, such as sensitivity and specificity. Holding any diagnostic test to the high bar of positively affecting patient outcomes would dramatically change the business and clinical landscape for imaging.

Thus, even though not implemented, it is possible that the draft policy will have far-reaching effects. We have invited multiple stakeholders to present their views of the implications of CMS’s actions. Matthew Budoff, a cardiologist, and Pamela Woodard, a radiologist, take the view of the physicians providing CTA services. Sean Tunis supports evidence development, Richard Justman takes the view of private payers, and Robert Honigberg presents a view from industry about the impact of the draft NCD.

The CTA Evidence Base Is Already Robust!

Matthew Budoff, MD, FACC
Harbor-UCLA Medical Center, Torrance, California

CARDIAC CTA IS A NON-INVASIVE IMAGING TECHNOLOGY for the diagnosis and evaluation of CAD. The amount of peer-reviewed research is growing at an unprecedented pace for a new modality. Over 200 studies were published since 2005, with 20 more coming out each month, including multicenter trials and outcome data. Over 2 years ago, regional Medicare carriers reviewed the data, published guidelines, and appropriateness criteria for CTA, and issued local coverage determination (LCD) policies, which provide reimbursement in all 50 states for CTA. In addition, United Health Group, Aetna, Cigna, and Humana have all decided to cover CTA after expert panels reviewed the available data.

The CMS mechanism of CED is a restricted form of a NCD reserved for medical technologies and treatments that are promising but for which comparative effectiveness data do not exist and are not likely to be available in the near future. In contrast, the use of CTA in a defined patient population is supported by sufficient clinical evidence that it should be considered a “proven” rather than a “promising” medical technology. For instance, a proper and beneficial use of CED is the lung volume reduction surgery for emphysema. A NCD with CED was instituted requiring enrollment of these patients in a trial for reimbursement. The outcome of the trial showed no benefit and a “no coverage” policy was instituted. Further, as a treatment, a reimbursement standard of improvement of outcomes is appropriate, but CTA is a diagnostic test and not a treatment.

For CTA, data are already available about improved short-term health outcomes compared with avoiding complications related to invasive angiography (3), a reduced need for invasive angiography with associated cost savings (4), and a large number of studies have demonstrated the high negative predictive value (~99%) of coronary CTA (5). As further evidence that CTA should be reimbursed, consider the status of CTA of the carotids, renal arteries, and peripheral vessels; all are covered with less data than exists for CTA. Similarly, there are more data for cardiac CTA than for many other diagnostic applications of CT that are covered by CMS.

There is no need for a CED for CTA; a robust evidence base is being compiled, with outcome studies and large diagnostic studies already underway. Two multicenter trials have just been reported and several outcome studies are enrolled and following patients (6,7). No other diagnostic test in...
cardiology has outcome data suggesting improved outcomes with testing. The decision that CTA be the first such widespread imaging modality for which demonstration of health improvement is a required condition of reimbursement will limit the Medicare population’s access to a clinically established diagnostic test that has demonstrated reduced risk and costs as compared with invasive angiography.

A Policy That Promotes Evidence Development Would Have Been Reasonable!

Sean Tunis, MD, MSc
Center for Medical Technology Policy
Formerly, Chief Medical Officer, CMS

COVERAGE WITH EVIDENCE DEVELOPMENT APPLIED BY CMS, with increasing frequency over the past several years, is intended to support the development of additional evidence about medical technologies when existing evidence is “promising” (8). Medicare applies this policy for those technologies for which there is a potential for substantial health impact on the Medicare population and when additional studies are more likely to be conducted with the benefit of reimbursement. The rationale for applying CED to CTA for symptomatic patients at intermediate risk of CAD depends heavily on whether the available evidence is considered to be promising. Medicare provides unrestricted coverage for those technologies for which the evidence is determined to be “adequate” to conclude that the item or service improved health outcomes, which is the standard used by the agency to identify “reasonable and necessary” services.

The distinction between promising evidence and adequate evidence is a matter of judgment, not a matter of science or fact (9). Experts and stakeholders have come to different conclusions regarding the quality of the existing evidence (10). Recent technology assessments from the Blue Cross Blue Shield Association, the Duke Evidence-based Practice Center, and the California Technology Assessment Foundation all concluded that the evidence for CTA does not support clinical utility. The most recent American Heart Association statement on cardiac imaging assigns a class IIa recommendation for CTA in these patients (conflicting evidence, divergence of opinion, or both; weight of evidence/opinion in favor) (11).

A number of multicenter trials and registry studies have been reported at professional meetings, but have not yet been published. Virtually everyone agrees that there are no published studies that demonstrate improved health outcomes for intermediate risk patients who undergo CTA. Some note that studies showing an impact on patient outcomes have rarely been done for cardiac imaging and many other diagnostic technologies and argue that it is unreasonable to expect such studies as a condition of reimbursement. Others assert that imaging and diagnostic studies, as with any health care intervention, must ultimately be judged on whether or not there are documented health benefits—in other words, whether the service lead to changes in care that eventually improve patient health.

Given this range of opinions, the conclusion by CMS in its proposed decision that the evidence for CTA in intermediate risk patients is promising but not adequate was not unreasonable. Based on the available evidence on CTA, it is possible to make plausible arguments that patients obtain net clinical benefit, and it is also possible to make plausible arguments that the impact on patient’s health is uncertain and could even be harmful (e.g., from radiation exposure or additional invasive testing resulting from false positive tests). The best way to distinguish between those alternatives would be to collect additional evidence, an outcome that CED would support.

In the final NCD (2), the CMS concluded that “no adequately powered study has established that improved health outcomes can be causally attributed to coronary CTA for any well-defined clinical indication, and the body of evidence is of overall limited quality and limited applicability to Medicare patients with typical comorbidities in community practice.” By the agency’s usual definition of “reasonable and necessary” services, coronary CTA did not meet the standard of being supported by evidence of improved health outcomes. However, the agency determined that the lack of evidence did not provide a sufficiently strong policy basis to reverse the existing coverage that had been approved by local Medicare contractors. Application of CED at the national level would have been considered a narrowing of coverage, and this mechanism for promoting the development of further evidence was not retained. Conducting additional studies that CMS hopes will provide evidence about the impact of coronary CTA on patient outcomes will be much more difficult in the context of the broad coverage now available through local policies.

What is left unresolved with the final Medicare policy is the wide gap...
between what some payers consider to be inadequate evidence of diagnostic utility and what some clinicians and product developers consider to be adequate. Furthermore, no progress has been made toward ensuring that the creation of more reliable evidence precedes, or at least accompanies, the widespread adoption of the next generation of imaging technologies. My hope would be that meaningful dialogue continues among the stakeholders about how to generate better evidence on the diagnostic utility of imaging technologies more rapidly and efficiently and to move toward greater consensus about the type of evidence that is appropriate for reimbursement. The Center for Medical Technology Policy was established to support collaborative efforts to develop evidence standards and strategies to efficiently develop that evidence (12). Ideally, we will not continually repeat the pattern of widely adopting these technologies based on expert opinion and limited evidence while hoping (too often in vain) that someone will take responsibility for conducting the studies necessary to determine with greater confidence whether we are actually helping or hurting patients.

**ACC and ACR Should Work Closely Together to Assist Physicians!**

Pamela K. Woodard, MD
Associate Professor of Radiology,
Washington University School of Medicine

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As a physician, I was concerned about an NCD for controlled clinical trial (CCT) reimbursement, especially one requiring CED on the part of the physician in order to get paid. Although not all patients are optimal candidates for CCT, I feel that it is important for those patients who would benefit from CCT to have access to it. Moreover, there are always exceptions to every coverage policy rule, and when exceptions arise, the best patient care would allow the physician to negotiate Medicare or Medicaid reimbursement for that patient at the local level—something that would not be an option if CMS instituted an NCD. Also, not all physicians are researchers. An NCD ruling linked to CED would have required private imaging practitioners with no research experience to participate in research trials in order to receive reimbursement. Thus, 1 of 2 things could have occurred: Some physicians might have opted not to participate in research trials, limiting access to CTA.

CMS, physicians and researchers now have the freedom to continue to perform multicenter randomized controlled trials and registries based on scientific design rather than a design created specifically to fill a reimbursement goal.

As before the CMS determination, it is necessary that the major professional societies with interest in cardiac imaging, such as the American College of Radiology (ACR) and the American College of Cardiology (ACC), continue to work together to promote research. Research options include both hypothesis-driven, multicenter randomized, controlled trials and nationwide registries. Randomized-controlled trials are necessary to pursue answers to specific clinical questions, and registries have the potential to provide long-term evidence based on imaging quality in the “real world.” Societies might have the biggest impact on registries. Both the ACC and the ACR, through their previous experiences with registries, are well equipped to provide the design, infrastructure, and data analysis to make a coronary CTA (CCTA) registry a success. These registries have the potential not only to provide a tremendous amount of data regarding appropriateness and outcome, but they also have the potential to provide immediate impact on health care by distributing quality assurance and appropriate data back to participating centers.

I strongly believe that the CMS decision was the correct one. The CCTA research will continue to flourish of its own accord, allowing
patients who could benefit from the coronary CT examination to have access to it.

We Respectfully Disagree with Some Conclusions in Draft NCD!

Richard A. Justman, MD
National Medical Director,
United HealthCare

ALTHOUGH UNITED HEALTHCARE UNDERSTANDS AND AGREES WITH THE NEED FOR AN NCD to be based upon published clinical evidence, and although we see the potential for overuse and inappropriate use of CTA, we respectfully disagreed with some of the conclusions in the proposed NCD.

The CTA is an advanced imaging technology intended to identify persons at risk of a cardiac event. It is less invasive than traditional coronary angiography. We believe that the CED approach should be reserved for medical technologies and treatments that are promising but for which comparative effectiveness data does not exist and is not likely to be available in the near future. The use of CTA in defined patient populations is supported by sufficient clinical evidence that it should be considered a “proven” rather than a “promising” medical technology.

Chief among these populations is the assessment of patients with known or suspected CAD. United HealthCare believes that clinical evidence supports the use of CCTA using 64-slice or greater technology for patients with: 1) chest pain syndrome and intermediate pre-angiography probability of CAD when the electrocardiogram (ECG) is uninterpretable or the patient is unable to exercise; 2) chest pain syndrome and prior uninterpretable or equivocal stress test results (exercise, profusion, or stress echo); 3) acute chest pain and intermediate pre-angiography probability of CAD, no ECG changes, and negative serum enzymes. In addition, we also believe that clinical evidence supports the use of CCTA using 64-slice or greater technology for the assessment of patients with known and suspected coronary anomalies and morphologic assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves, and morphologic evaluation of coronary arteries in patients with new onset heart failure to assess etiology.

In summary, CTA using 64-slice or greater technology should be considered reasonable and medically necessary for the assessment of patients with known and suspected coronary anomalies and morphologic assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves, and morphologic evaluation of coronary arteries in patients with new onset heart failure to assess etiology.

NCD for CTA Sets a Troubling Precedent!

Robert Honigberg, MD
Chief Medical Officer, GE HealthCare

THE NCD FOR CORONARY CTA (1) PROPOSED BY CMS should be a wake-up call to the cardiology and medical imaging community. Both groups must be more collaborative and proactive in generating multicenter clinical data to validate the diagnostic accuracy of new imaging technologies for specifically defined patient populations.

However, CMS and other payers need to be part of the collaboration rather than serving primarily as a means for technology assessment. In the summer of 2006, MedCAC convened to assess coronary CT and magnetic reso-
coverage was in place in all 50 states through local coverage decisions. In this context, the announcement of CMS’s national coverage analysis for CTA in the summer of 2007 was cause for much surprise and great concern. The key concern was that most of the literature for multislice CCTA was still dominated by weaker studies on 16-slice technology and the publication lag time for multicenter 64-slice CTA trials might affect the outcome of the analysis by excluding key trials such as CorE64 (Coronary Evaluation Using Multidetector Spiral Computed Tomography Angiography Using 64 Detectors) trial, ACCURACY (The Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Coronary Angiography), SPARC (Satraplatin and Prednisone Against Refractory Cancer) trial, and a host of resource use and economic studies.

Although not enacted as a final rule, the preliminary decision memo for CTA still sets some troubling precedents. First, the memo completely negates all existing local Medicare coverage. In effect, CMS chose the most restrictive coverage and most burdensome approach for patients and providers. Coverage with evidence development has been characterized by CMS as a method for expanding coverage, not restricting it. Second, the memo was a directional move to hold diagnostic technologies accountable for clinical outcomes, which is a complex relationship dependent upon treatment selection decisions, patient compliance patterns, and geographic variations in the standard of care.

The final NCD for CTA will now allow for clinical and health economic research in the pipeline to be published. It is important that we remember the premise of the preliminary decision memo as a precedent to raise the bar for outcomes data—not only for CTA but also for other diagnostic technologies. We need to stay ahead of the curve to validate diagnostic accuracy in patient populations and understand how the technology affects the downstream use of health resources.

**REFERENCES**


