

# SIEMENS

January 11, 2008

Steve E. Phurrough, MD, MPA

Director

Coverage and Analysis Group, CMS

Re: CTA

Mailstop C1-09-06

7500 Security Blvd.

Baltimore, MD 21244-1850

Marcel Salive, MD, MPH

Director, Division of Medical and Surgical Services

Joseph Chin, MD, MS

Lead Medical Officer

JoAnna Baldwin, MS

Lead Analyst

Dear Drs. Phurrough, Salive, and Chin and Ms. Baldwin:

**Comment on Proposed Decision Memorandum for Computed Tomographic  
Angiography (CAG-00385N)**

This letter is on behalf of Siemens Medical Solutions, one of the leading manufacturers of modern high-resolution CT scanners. We are deeply

concerned with the CMS Coverage and Analysis Group's proposed finding that cardiac CTA is not currently "reasonable and necessary" for the diagnosis of coronary artery disease and its proposed essentially non-coverage determination.

This proposed national Medicare non-coverage determination would reverse determinations made by each of Medicare's local contractors over the past few years which provide coverage for this technology for this diagnostic purpose. If implemented, this proposed determination would mandate a significant shift in medical practice - denying physicians the ability to provide precise early coronary artery disease diagnosis to Medicare beneficiaries. We strongly urge CMS to reconsider this proposed policy.

#### General Comments:

Cardiac CTA is a proven technology and is the only high resolution non-invasive way to visualize coronary artery disease - the leading cause of death of Medicare beneficiaries. All other technologies to diagnose coronary artery disease are either low resolution or invasive.

Cardiac CTA has gained wide spread acceptance and usage by thousands of physicians because it offers a combination of high diagnostic precision without the risk of the complications of an invasive procedure. Current Local Coverage Determinations as well as many private insurance coverage policies throughout the United States reflect the broad consensus among Medicare Carrier and private payer medical directors and practicing physicians regarding indications for this test. Given the widespread morbidity and mortality of complications resulting from late-diagnosed coronary artery disease, which include heart attack, congestive heart failure, and arrhythmias (each of which cost Medicare many billions of dollars per year), it is surprising that this relatively low cost, proven

diagnostic technology has been singled out for “Coverage with Evidence Determination” standards that will effectively result in total non-coverage for the vast majority of Medicare beneficiaries who could benefit from the procedure. With American Heart Association statistics showing 325,000 Americans dying of sudden undiagnosed heart disease each year, it is difficult to understand the inference made by CMS that heart disease is over-diagnosed and in need of new diagnostic limitations. An NCD that effectively cuts off all coverage for cardiac CTA would be a precipitous event forcing physicians and patients to revert to higher risk, costlier and often more imprecise tests.

The standard articulated in the proposed NCD that this diagnostic test needs to have proven “health outcomes” establishes an unprecedented and unreasonable standard for diagnostic tests, such that each diagnostic test would potentially need to have all or most of the downstream treatments re-evaluated since there is no clear way of showing outcome changes from a diagnostic test in the setting of a clinical trial without evaluating the resulting treatments as well. While an insistence on outcomes for certain diagnostic testing situations where the test and subsequent treatment are investigational may well be appropriate, to insist that we currently have no “reasonable” idea on how to treat coronary artery disease discovered by cardiac CTA simply ignores much of modern coronary disease management. There are tens of thousands of peer-reviewed research publications on how to treat coronary artery disease with corresponding outcomes. There is no credible data to suggest that coronary lesions diagnosed by cardiac CTA are so materially different from those diagnosed by cardiac catheterization as to require reanalyzing treatment outcomes. In fact, modern high temporal and spatial resolution cardiac CT scanners have higher sensitivity and specificity than almost any other non-invasive diagnostic test used in modern medicine.

Clinically, we believe that the types of potentially fatal lesions that can be seen on cardiac CTA (such as a 90% left main coronary artery blockage) have an

obvious impact on patient outcome in way that makes cardiac CTA “reasonable and necessary”. Conversely, with the significant morbidity and mortality risk with missed myocardial infarctions, the ability to efficiently evaluate a symptomatic patient and show that they have no coronary artery disease is valuable and “reasonable and necessary” as well. There is no better technology to safely, effectively, and efficiently rule out coronary artery disease. The NCD proposal document shows that with each of the modern cardiac CT studies where a Negative Predictive Value is cited (Ehara NPV 95%, Ropers NPV 100% per segment, Heuschmid NPV 99%, Weustink NPV 95%, Scheffel NPV 99.4%, Olivetti NPV 97.3%) that NPV and the corresponding ability to rule out CAD is extremely high.

We are also concerned that “Coverage with Evidence Determination” process as applied to cardiac CTA does not reflect the clinical context of medical decision making. Physician decisions for a patient presenting with symptoms that may well reflect lethal coronary disease are governed not by questions about the absolute perfection of one technology over another but by the relative merits of each possible choice. To evaluate cardiac CTA without putting it into context of competing choices such as the inherent high uncertainty and limited off-hours availability of nuclear studies, the risk of death with invasive catheterization or simply the risk of poor outcome if no testing is performed appears inconsistent with optimizing health for Medicare patients.

In addition to these overall issues that we see with the proposed NCD, we have identified a number of specific process and clinical issues.

#### Process Issues:

- 1) CT technology has evolved at a rapid pace. Much of the NCD deals with earlier generation 4 and 16 slice technologies. It is inappropriate to

evaluate modern high temporal and spatial resolution CT scanners together with these older technologies as there are clear differences between the technical capabilities and clinical results of current and prior CT technology.

- 2) The literature review noted in the NCD appears to be selective. There appears to be a dismissal of the diagnostic test literature comparing cardiac CTA to competing technologies and limited consideration of practice settings and patterns. For example, though the NCD denies coverage for emergency department use of cardiac CTA to diagnose coronary artery disease, there are no citations from the peer-reviewed emergency medicine literature. In the emergency medicine setting, there is no sense of the disproportionate role that lengthy ER “soft rule-outs of MI” play in US ED overcrowding.
- 3) The proposal provides no criteria regarding how studies falling under the narrow coverage guidelines would be approved nor under what circumstances Medicare would reconsider its decision. There should be explicit acknowledgement that if only new studies, pre-approved by Medicare and published in the peer-reviewed literature, are to be considered, that this proposal effectively means at a practical minimum a three to four year delay in coverage for this life-saving test.
- 4) The process does not acknowledge the costs that someone has to bear of doing the mandated trials.
- 5) The process does not incorporate an analysis of costs to Medicare and Medicare beneficiaries if cardiac CTA is not covered. Competing Medicare covered technologies such as nuclear studies and cardiac catheterization are much more labor intensive and costly studies. Additionally, the NCD does not include outcomes modeling of the

increased system and patient costs of heart attack, stroke, congestive heart failure, arrhythmias and premature death that will follow coverage denial extrapolating from today's pattern of widespread under-diagnosis of coronary artery disease.

- 6) The tradition of the "coverage with evidence development" process has been just that – coverage WITH evidence development. This proposed NCD effectively changes that policy to "non-coverage UNTIL evidence development".

#### Clinical Issues:

- 1) The described clinical scenarios ("symptomatic patients with chronic stable angina at intermediate risk for CAD" and "symptomatic patients with unstable angina at a low risk of short-term death and intermediate risk of CAD") are clinically imprecise and confusing. Labeling a patient with the term "angina" (of any duration) suggests that the patient already has a diagnosis of coronary artery disease in the common usage of the word. This implies that cardiac CTA would be an add-on study following whatever type of study gave the patient the original diagnosis of coronary artery disease.
- 2) Coronary artery disease can present with a variety of symptoms, not just chest pain ("angina"). For example, research by McSweeney et al shows that women with an acute myocardial infarction are as or more likely to present with shortness of breath or fatigue (McSweeney JC et al. Circulation 108:2619-23; 2003).
- 3) Often CTA is ordered not just to assess coronary artery disease but for other life threatening syndromes such as aortic dissection or pulmonary

embolus. The NCD provides no consideration to the broader indications around CTA that are simply unavailable with competing modalities such as treadmill, SPECT or serial cardiac enzymes and EKG's.

- 4) Using the concept of Framingham Risk scores only makes sense with patients who are asymptomatic. As soon as you have symptoms, the risk of CAD changes dramatically. A Medicare patient presenting with "crushing, substernal chest pressure and diaphoresis" does not fit into a "low risk" or "intermediate risk" category no matter what their Framingham score.
- 5) There is an overall confusion in the NCD document between what the various CCTA studies generally cite as "high risk" (a worrisome set of symptoms in a patient at risk) with the NCD's general use of the same "high risk" phrasing to refer to patients with clear indications to go to the cath lab (positive EKG, positive cardiac enzymes).
- 6) By selective use of terms such as "angina" and heavy reliance on cardiac cath as a gold standard, CMS is missing the opportunity to provide its beneficiaries with treatment based on the stunning revolution in understanding around the role of plaque in coronary artery disease. Cardiac CTA is the only high reliability non-invasive way to diagnose coronary plaque. "Lumen-based" testing such as nuclear studies, treadmill and cardiac cath can only diagnose plaque after cardiac muscle has been placed at immediate risk.

We think that the current real world use of CTA by physicians to diagnose coronary artery disease is something to build on to gather more evidence about specific situations where CTA can be used in place of invasive or inconclusive tests. To summarily cut off Medicare beneficiary access to CTA, as is proposed

in the NCD, is the wrong course of action to answer the questions that CMS has expressed with respect to this technology.

Given the current widespread coverage of CTA in the United States, we believe that steps should be taken to use this practical experience to inform and guide a national Medicare coverage determination. We think that conditional coverage—coverage in return for evidence, explained in the agency’s Coverage with Evidence Development Guidance Document—provides a pathway to resolve outstanding evidentiary questions that exist with respect to CTA. We do not think that this coverage should end, as proposed in the NCD, while CMS entertains submissions for research studies that address the CMS concerns.

Recommendation:

We recommend that CMS reconsider its proposed NCD for Cardiac Computed Tomographic Angiography for the Diagnosis of Coronary Artery Disease. During this reconsideration, we suggest that:

- CMS consider the evidence omitted from consideration in this proposed NCD.
- CMS identify circumstances in which CTA is “reasonable and necessary” based on the medical specialty guidelines (which reflect both the clinical evidence and medical consensus based on the practical difficulties of managing patients with coronary artery disease).
- CMS assess the clinical and financial implications of noncoverage of cardiac CTA including use of other more expensive or more invasive tests and the higher likelihood of Medicare patients presenting with heart attack, CHF, arrhythmias and sudden death due to decreased early diagnosis of CAD.

- CMS engage in discussions with the various medical specialty societies and technology manufacturers concerning any further data gathering needed. Any further data requirements mandated as part of a Coverage with Evidence Determination policy should be designed to minimize the cost and compliance burdens.
- CMS allow the local carrier coverage determinations to remain in place throughout the duration of any further studies.

If CMS proceeds with the NCD as proposed, we would recommend a delay in implementation of at least one year to allow formulation of research without gaps in coverage. This will have the additional benefit of allowing the multiple major studies currently in the publication process to be available for CMS consideration.

\*\*\*\*\*

Thank you for considering these comments. Please feel free to contact me directly if you have questions, or wish any further information on any of the various cardiac CTA technologies that we offer.

Sincerely,

/s/

Don Rucker, MD  
VP, Chief Medical Officer  
Siemens Medical Solutions USA  
51 Valley Stream Parkway  
Malvern, PA 19355