



July 13, 2007

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

Re: NCA for Computer Tomographic Angiography (CAG-00385N)

Dear Dr. Chin and Ms. Baldwin:

The American College of Cardiology (ACC) and the American College of Radiology (ACR) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) National Coverage Analysis (NCA) on Computed Tomographic Angiography (CAG-00385N).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy.

The ACR, representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists is also a non-profit professional medical specialty society with a mission to serve patients by improving the quality of patient care, through advancing the science of radiology, providing continuing education, conducting research for the future of radiology, and shaping health care coverage and policy.

We are submitting a joint comment letter at this time because both of our respective organizations share the same general concerns with CMS' decision to open an NCA of Computed Tomographic Angiography (CTA). The ACC and ACR strongly recommend the agency not adopt a National Coverage Decision (NCD) on CTA at this time.

While we intend to submit more detailed comments upon review of CMS' subsequent draft NCD memo, at present our general concerns and recommendations are as follows:

1. The decision whether to cover CTA should be left to the local Carriers, who have more hands-on access to the results of its use on beneficiaries at this time;

2. The NCA, as written, is mistakenly setting an inaccurate standard for a non-invasive diagnostic test in asking for data on CTA's impact on health care outcomes. However, this field is progressing rapidly and outcomes studies documenting the diagnostic value, prognostic value and cost effectiveness are being published; and
3. The NHIC California Medicare Local Coverage Decision (LCD) is an excellent example of the model policy process. This policy is a strong adaptation of the model LCD created by the ACC and ACR discussed below, and could serve as a basis for a national policy should CMS determine a NCD to be more appropriate than the recommended LCD process.

Coverage of CTA should be Left to Local Carriers:

The ACC and the ACR consider implementation of an NCD for CTA unnecessary at this time. Historically, the NCD process has only rarely been used to establish national coverage guidelines for diagnostic imaging procedures. Medical necessity for the vast majority of diagnostic imaging studies has been established by the LCD process. We feel strongly that CTA should continue to be covered at the local level via the model policy and LCD processes.

For two years, our societies have been working with the local Medicare contractors to develop appropriate coverage policies for coronary CTA, and the majority of Medicare contractors have developed local policies for coverage. The Contractor Medical Directors are able to work closely with the physician Contractor Advisory Committee members from both the providers of CTA and the ordering physicians. Thus they are able to follow how CTA is being integrated into practice in their community and can change their LCDs either as indications develop or on the basis of inappropriate volume.

In addition to the local Carrier process, the ACC and ACR developed a model LCD for CTA with broad input from Carrier Medical Directors as well as the private payor community—resulting in a comprehensive tool that has proven to be influential on current LCDs for CTA. Because NCDs are "one-size-fits-all" policies and are difficult to modify quickly in unanticipated situations, we believe the authority to make such coverage determinations for CTA is best exercised at the local level.

By Seeking Data on Health Outcomes Related to CTA, the NCA Mistakenly Applies an Inaccurate Standard for Non-Invasive Diagnostic Tests:

If, however, CMS determines that some degree of national consistency in coverage for cardiac CTA is in the best interests of Medicare patients, the ACC and ACR believe that sufficient evidence exists to provide guidance about indications that should be included in a national coverage determination. Prior to discussing this evidence, however, we must note that the questions raised by the NCA tracking sheet do not accurately identify the issues that a coverage policy for CTA could potentially address. Specifically, the statement: "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]" does not properly articulate the purpose of CTA.

CTA is a highly useful tool for physicians to make better, more prompt diagnoses without employing invasive procedures (i.e. catheter deployment) that may introduce risks of complications in all patients—especially for those whose overall physical condition may heighten any existing risks. While CTA may play an important role in the overall treatment of a patient (i.e. correct diagnosis), its use, alone, will not necessarily produce “better outcomes (*sic*),” since the subsequent course of treatment and other factors (e.g. co-morbidities, etc.) will have far greater influence in affecting a patient’s health outcomes.

Applying the standard of "improved patient health outcomes" to diagnostic tests is problematic and totally ignores the value of a negative examination. For example, in studying a cohort of patients being treated for pneumonia, no one would question the value of a chest radiograph in excluding the disease, yet it is impossible to develop improved patient health outcome data for pneumonia from a negative chest radiograph as these patients never had the disease. Similarly, CTA as a diagnostic test must be effective at excluding the coronary artery disease.

The overwhelming evidence from the literature is that CTA can accurately exclude coronary artery disease. In this regard, CTA will replace nuclear medicine imaging and catheter angiography in numerous patients undergoing a chest pain workup. Because these patients do not have the disease, evaluating a long-term health outcome for these patients is problematic. Since coronary events would be extremely rare in the short-term, developing data proving that the patients benefited by having the study is impossible. The value of CTA for these patients has to be seen in terms of decreasing the downstream diagnostic interventions which would have otherwise been necessary based on the patient's clinical findings.

For example, the use of CTA for diagnosis of carotid stenosis has significantly decreased the number of cerebral catheter arteriograms. As a diagnostic study, CTA must also be able to identify and characterize disease. Studies comparing CTA to catheter coronary angiography are quite favorable and results are being used to triage patients into groups that have coronary artery disease (CAD) but do not need catheter angiography. Finally, by its ability to detect non-stenotic soft plaque, CTA has the ability to detect CAD in patients that would have had a negative nuclear medicine and catheter angiography. These patients are at risk for future adverse coronary events and initiation of medical therapy in these patients may decrease the number of future myocardial infarctions.

In sum, CTA is not a preventive or therapeutic procedure. It is designed to detect and characterize coronary artery disease and other vascular diseases of the heart. The beneficial outcome for patients can only be expressed in terms of preventing downstream and sometimes invasive diagnostic examinations and in detecting the disease in patients who would have otherwise had a negative conventional workup. The value of a negative examination cannot be over emphasized.

**NHIC's LCD for CTA is an Excellent Example of the Model LCD Process'
Effectiveness:**

A number of local Medicare carriers have used a model LCD in developing their own policies. In particular, NHIC's (Medicare's Part B Carrier for California) LCD for Multislice or Multidetector Computed Tomography Angiography of the Heart and Great Vessels (L22517) is an excellent example of how the collaborative efforts between ACC and ACR, as well as Contractor Medical Directors and other stakeholders to develop a model LCD demonstrate the effectiveness of a local approach to CTA coverage decisions (*See Attachment A*). It is our understanding that this LCD enjoys strong endorsement from Contractor Medical Directors in general beyond only NHIC's, particularly since numerous clinical experts consulted during its development formed a subgroup for looking critically at literature and indications. Additionally, it should be noted that the vast majority of CMDs cover the Category III codes for coronary CTA and most of these approvals are based on the model LCD.

Further, this model LCD also covers indications for CTA use that are not addressed in the NCA, but are supported by current research data. While the data on efficacy of CTA is still forming, it exists in sufficient amounts to support its continuing, or even expanded, coverage under Medicare. The ACC and ACR recommend the following be considered for inclusion in any NCD on CTA:

A. Expand the Indications for CTA Use:

There are several important indications for CT angiography that have not been listed among those in the current model LCD developed by ACC and ACR.

The American Heart Association (AHA) has recently published a Scientific Statement on Cardiac CT, and outlined two important indications that received Class IIa indications for use¹. These were:

- 1) For the assessment of obstructive disease in symptomatic patients (Class IIa)
- 2) Use CT as one of the first choice imaging modalities in the workup of known and suspected coronary anomalies (Class IIa)

The societies have also assessed CTA and developed appropriateness criteria. The methodology used for the appropriateness criteria was rigorous and the results are

¹ Budoff MJ, Achenbach S, Blumenthal RS, Carr JJ, Goldin JG, Greenland P, Guerci AD, Lima JAC, Rader DJ, Rubin GD, Shaw LJ, Wiegers SE. Assessment of Coronary Artery Disease by Cardiac Computed Tomography, A Scientific Statement From the American Heart Association Committee on Cardiovascular Imaging and Intervention, Council on Cardiovascular Radiology and Intervention, and Committee on Cardiac Imaging, Council on Clinical Cardiology. *Circulation* 2006; 114 (16): 1761-91.

attached, along with a description of the approach used to reach conclusions².

These appropriate indications (scores 7-9) include:

- Un-interpretable or equivocal stress test (exercise, perfusion, or stress echo)
- Intermediate pre-test probability of CAD
- Initial evaluation of new onset or atypical chest pain or heart failure
- Evaluation of cardiac mass (suspected tumor or thrombus)
- Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery)
- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation
- Noninvasive coronary vein mapping prior to placement of biventricular pacemaker
- Noninvasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization
- Evaluation of congenital cardiac and coronary anomalies

B. Current Data Demonstrates Accuracy of CTA – i.e. Negative studies avoids invasive testing risk and trauma – (From AHA Statement):

A negative test (normal coronaries or non-obstructive disease) on CTA makes the presence of significant luminal obstructive disease highly unlikely (negative predictive power on the order of 95-99%). Over the last two years, 16- and 64-row Computed Tomography has been validated to have a very high negative predictive power to ‘rule out’ obstructive disease in symptomatic persons in an outpatient chest pain environment, in congestive heart failure of unknown etiology and emergency department evaluation of chest pain syndromes.

A recent study³, in concordance with prior studies, demonstrates a very high negative predictive power for the presence of obstructive CAD (100% in this study). Thus, the strength of CTA remains in the ability to rule out disease (negative tests), so that further evaluation (including stress testing, functional tests and angiograms) can be avoided safely in these patients, remains a primary use of CTA in recently published Appropriateness Criteria and American Heart Association Guidelines⁴. Other studies have demonstrated this high negative

² Hendel RC, Patel MR, Kramer CM, et al. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging. J Am Coll. Cardiol: 2006: 48; 1606 –13.

³ James K. Min , Leslee J Shaw, Richard B Devereux, Peter M. Okin, Jonathan W. Weinsaft, Donald J. Russo, Nicholas J. Lippolis, Daniel S. Berman, Tracy Q. Callister. Prognostic Value of Multidetector Coronary CT Angiography for Prediction of All-cause Mortality. Journal of the American College of Cardiology (in press).

⁴ Leslee J. Shaw, Daniel S. Berman, James K. Min, Donna Polk, Tracy Q. Callister, Prognosis by coronary computed tomographic angiography: a comparison with myocardial perfusion SPECT. American Heart Association, Chicago, IL 2006. (Circulation, October 2006) (Abstract).

predictive power, giving clinicians confidence that a negative CTA (no obstructive disease seen), will result in a normal or near normal CATH.

These studies suggest that CTA would allow reliable triage of patients with suspected coronary artery disease, with decreased utilization of downstream testing after a normal or near-normal CTA. The study by Raff et al. demonstrated that over 67% of patients presenting to the emergency room had normal or near normal CTA studies and those with negative studies demonstrated freedom from major adverse events over 6 months (100% safety)⁵.

C. Prognostic and Cost Data on Use of CTA Supports Continued Medicare Coverage:

Several recently published ongoing studies⁶ indicate that CTA has prognostic value, particularly when no abnormalities are found. In one study (in press), during a 15-month follow-up of 1,127 patients presenting with chest pain, CTA identified individuals at increased risk for all-cause death, with increasing risk for more severe or proximal (left main) disease. Furthermore, normal CT angiograms identified patients at extremely low risk for death⁷. Two additional outcome studies have demonstrated 100% short term event-free survival after a normal or near normal CTA (i.e., no obstructive disease seen)⁸. Thus, these patients can be managed medically without the need for coronary angiography. This results in a significant decrease in downstream costs from invasive testing⁹. A sensitivity analysis recently examined cost implications if CTA was performed prior to invasive coronary angiography for patients with mildly abnormal or equivocal SPECT perfusion

⁵ James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Differences in Episode Based Costs for Coronary Computed Tomographic Angiography vs. Myocardial Perfusion Imaging for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007.

⁶ James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Hospitalization Outcomes in Individuals Undergoing Coronary Computed Tomographic Angiography, Myocardial Perfusion Imaging or Cardiac Angiogram Catheterization for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007. See also footnotes: 3, 4, 5, 7 and 8.

⁷ See 3 above.

⁸ Gopal A, Ahmadi N, Young E, Weinberg N, Tiano J, Amelia Y, Flores M, Witteman AM, Holland TC, Mao SS, Fischer H, Budoff MJ. Cardiac computed tomographic angiography in an outpatient setting: an analysis of Patient Outcomes over a 30 month period. J Am Coll. Cardiol 2007; 49:114A; and

Lesser JR, Flygenring B, Knickelbine T, et al. Clinical utility of coronary CT angiography: coronary stenosis detection and prognosis in ambulatory patients. Catheter Cardiovasc Interv. 2007 Jan; 69(1): 64-72.

⁹ Cole JH, Chunn VM, Morrow JA, et al., Cost implications of initial computed tomography angiography as opposed to catheterization in patients with mildly abnormal or equivocal myocardial perfusion scans. Journal of Cardiac Computed Tomography July 2007; 1(1):21-26.

images. This study demonstrated an average savings of \$1454/patient when using coronary CTA as the “gatekeeper” for invasive coronary angiography¹⁰.

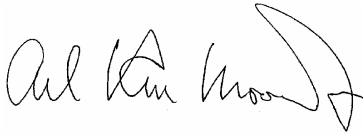
The ACC and ACR reiterate their appreciation to CMS for the opportunity to comment on the NCA for Computed Tomographic Angiography. Our organizations are eager to assist CMS in developing any further changes to this policy, and would welcome such an opportunity. If you have any questions, please contact:

- Sergio Santiviago, Senior Specialist, Regulatory Affairs, at ssantivi@acc.org or Rebecca Kelly, Director of Regulatory Affairs, at rkelly@acc.org;
- Anita Pennington, Economics and Health Policy Analyst, at apennington@acr.org or Maurine Dennis, Senior Director of Economics and Health Policy, at msdennis@acr.org.

Sincerely,



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President



Arl Van Moore, Jr., M.D.
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cc: Jack Lewin, M.D., CEO
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¹⁰ See 9 above.