



AMERICAN
COLLEGE of
CARDIOLOGY

ACR™
AMERICAN COLLEGE OF
RADIOLOGY



AMERICAN SOCIETY OF
NUCLEAR CARDIOLOGY



NASCI

North American Society for Cardiac Imaging

January 11, 2008

Steve E. Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-09-06
Baltimore, MD 21244-1850

Re: Proposed National Coverage Determination for Coronary CT Angiography (CAG-00385N)

Dear Dr. Phurrough:

The following comments are submitted jointly by the American College of Cardiology, American College of Radiology, American Society of Nuclear Cardiology, North American Society of Cardiovascular Imaging, Society for Cardiovascular Angiography and Interventions, and the Society of Cardiovascular Computed Tomography (the Societies).

The Societies referenced above appreciate the opportunity to comment on CMS' proposed national coverage determination (NCD) for coronary computed tomography angiography (CCTA). We appreciate CMS' interest in reviewing this state-of-the-art diagnostic tool and understand that CMS has a responsibility to ensure that covered services are "reasonable and necessary" for the Medicare population. However, we respectfully disagree with CMS' conclusions in this proposed coverage determination and believe that if implemented, the policy would have a profoundly negative impact on Medicare beneficiaries by limiting needed access to this technology for clinically appropriate indications.

We strongly urge CMS to maintain the current coverage status for CCTA; that is, CMS should continue to allow local Medicare carriers to determine coverage through the Local Coverage Determination (LCD) process. The LCDs now in place for all 50 states and the District of Columbia permit access to this important diagnostic tool for many Medicare beneficiaries undergoing evaluation for coronary artery disease (CAD). The analysis presented in the proposed decision memo simply does not support establishment of what will effectively be, in practice, a national non-coverage policy for the vast majority of Medicare patients.

If CMS does choose, however, to establish a national coverage policy, the Societies recommend national coverage without requiring evidence development for at least the following indications:

- Symptomatic patients with chronic stable angina or anginal equivalent and an intermediate pre-test probability of CAD;
- Symptomatic patients with possible acute coronary syndrome (ACS), a low risk of short term death and an intermediate probability of CAD;

- Assessment for presence and course of coronary artery anomalies;
- Coronary artery evaluation in individuals in whom prior clinical non-invasive coronary artery test data (e.g., ECG or imaging results) are equivocal or discordant;
- Assessment of bypass graft location (e.g., internal mammary artery) prior to surgical intervention in patients undergoing repeat sternotomy; and
- Coronary artery evaluation in patients undergoing non-cardiac surgery.

We will discuss these recommendations, and the substantial clinical research supporting them at greater length below.

Further, our recommendation that CMS not adopt this proposed NCD is based on a critical analysis of the proposed decision memo's findings and provisions. Our comments address the following points:

- CMS did not conduct an adequate, thorough analysis of all available relevant evidence. For example, approximately three fourths of the available studies on 64 slice CT scanners were not considered;
- Existing statements define appropriate use of CCTA;
- Clinically valuable indications for CCTA that are well supported by existing evidence are excluded from the proposed coverage;
- Definitions of patient populations for the proposed coverage with evidence development (CED) are inaccurate;
- The questions CMS has outlined for clinical studies to qualify for CED are inappropriately defined and are unlikely to yield beneficial information; and
- LCD status has fostered the development of ground breaking clinical trial research and registry data collection to answer questions about the utility of CCTA. The proposed NCD will only slow the development of evidence by academia, societies and registries rather than accelerate it.

Evidence Not Evaluated in the Proposed Decision Memorandum:

Before concluding this National Coverage Analysis (NCA), the Societies again emphatically recommend that CMS must consider the entirety of available published evidence before proposing to limit beneficiary access to this valuable diagnostic tool. A thorough and complete review includes consideration of the clinical indications agreed upon by expert consensus of the professional societies. Again, we wish to point out to the agency that approximately three fourths of the available evidence with 64-slice CT scanners has not been considered in the draft proposal. It is critically important that CMS modify its major premise used in forming the basis of the proposed NCD—the notion that CCTA must improve health outcomes. The Societies note that it has been well-established in medicine that no diagnostic test improves health outcomes by itself; only the resulting therapeutic interventions may do so. This is true for the simple reason that even in situations where a correct diagnosis is made, any number of variables affecting treatment (e.g. co-morbidities)—including the course of treatment itself (i.e. appropriateness, timeliness, patient cooperation, etc.)—may lead to poor health outcomes irrespective of whether the diagnosis was correctly issued due to CTA or other modalities.

Coronary CT angiography by multidetector computed tomography (MDCT) represents a major development in the field of non-invasive cardiac imaging, complementing pre-existing non-invasive cardiac testing in a manner heretofore not possible. The rapid evolution of MDCT technology resulted in widespread acceptance of CCTA within the field of cardiac imaging in 2005, when 64-

slice MDCT scanners first became commercially available. In the short time since its introduction, over 200 studies have been published dedicated to coronary angiography with the use of MDCT scanners of at least 64-slices, with additional articles defining the usefulness of CCTA and its numerous clinical applications arising in an exponential fashion. It appears that CMS excluded from review significantly more published manuscripts with 64-slice CCTA than were included in the coverage analysis.

The contemporary nature of the majority of these manuscripts precluded them from evaluation during the health technology assessment by the Agency for Healthcare Research and Quality (AHRQ) in 2006, as well as the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) review (2006). Already, the available evidence supporting the clinical utility of CCTA is dramatically different than it was during the AHRQ and MedCAC reviews, and has evolved considerably even during the drafting period of the proposed NCD.

The Societies again note that the proposed NCD does not fully consider all of the available evidence; as the standard of practice in 2007 is to perform CCTA with MDCT scanners of 64-slices, the Societies encourage CMS to consider the large numbers of 64-slice CCTA studies omitted from the proposed NCD in lieu of other studies involving outmoded 4-, 8-, and 16-slice MDCT scanners. The Appendix details these additional studies in a manner similar to that employed for the current proposed NCD. While 8 manuscripts employing 40- or greater slice CT scanners were evaluated, 25 full manuscripts using this contemporary level of CT scanner were not considered (Appendix).

On the basis of the combination of new evidence and prior data using 64-slice CCTA, the Societies urge CMS to reconsider the appropriateness of a national coverage determination. Should CMS proceed with a NCD, the Societies again strongly petition CMS to fully consider all currently available studies using 64-slice CCTA.

Existing Statements Define Appropriate Use of CCTA:

The Societies also strongly support the use of scientific statements and appropriateness criteria as a vital component of health quality metrics, and believe that critical pathways should be established to ensure that new imaging technologies are used solely for the benefit of patients. Currently, there are four multi-society manuscripts that have been published that evaluate the appropriateness of CCTA for use in differing clinical situations (complete citations are included in references at the end of this comment letter):

1. 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 (2006). This multi-society document agreed that there were three indications where the weight of evidence/opinion was in favor of usefulness/efficacy:
 - A. Assessment of obstructive coronary disease in symptomatic patients;
 - B. Follow-up after Coronary Bypass Surgery; and
 - C. Definition of anomalous coronaries.

Notably, only the first of these indications was referenced in the proposed NCD.

2. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR 2006 appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging: a report of the

American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. This contemporary multi-society document examined the appropriateness of 39 indications for CCTA using a rigorous methodology with a panel of varied composition, including non-imaging participants. Although some indications were scored as uncertain or inappropriate, 13 indications were considered appropriate.

3. Use of multidetector computed tomography for the assessment of acute chest pain: a consensus statement of the North American Society of Cardiac Imaging and the European Society of Cardiac Radiology.
4. Consensus Update on the Appropriate Usage of Cardiac Computed Tomographic Angiography: a report of the Society of Cardiovascular Computed Tomography and the North American Society for Cardiac Imaging.

Similar to the rapid changes in CCTA technology, the clinical utility of this technique is also dynamic. Reflecting this, documents #1 and #2 (referenced above) were written at a stage when few studies evaluating 64-slice CCTA were available. The rapid evolution of CCTA necessitated further clinical evaluation, and research has largely met this demand for additional information, as reflected in documents #3 and #4 (referenced above) among many others.

As mentioned previously, Medicare Carriers in all 50 states and the District of Columbia, have evaluated CCTA through the local coverage determination process, and have provided reimbursement for CCTA under well-defined indications. In addition, as noted in previous publications (such as document #2), the various professional societies involved with CCTA have developed and published appropriateness criteria to encourage improvement in quality of care and reduce inappropriate use of CCTA. These two factors currently permit, through the LCD process, clinically appropriate nationwide access to CCTA when it is clinically indicated.

Again, we strongly encourage CMS to reevaluate the clinical value and appropriateness of CCTA with the available evidence at hand.

Clinically-Valuable Indications of CCTA Excluded from Proposed Coverage:

The proposed NCD states that “all other uses of cardiac CTA for the diagnosis of CAD are non-covered.” This recommendation ignores several well-established applications of CCTA in patient populations not described in the proposed NCD. Among others, these indications include:

1. Assessment for presence and course of coronary artery anomalies – The Societies assert that CCTA is currently the reference standard for coronary artery anomaly assessment, and Medicare beneficiaries should be eligible for coverage without evidence determination.
2. Coronary artery evaluation in individuals in whom prior clinical non-invasive coronary artery test data (e.g., ECG or imaging results) are equivocal or discordant. Discordance regarding diagnosis of CAD or risk of cardiac event can occur at the level of:
 - A. Clinical symptoms in relation to stress testing results;
 - B. Exercise treadmill testing in relationship to stress imaging results; and

C. Within stress imaging results themselves.

Such subjects are often referred for further evaluation by invasive coronary angiography and constitute a high proportion of individuals in whom no obstructive coronary artery stenosis is later found. Examples of such discordance include the following:

- D. When a patient with typical angina has an equivocal stress imaging test;
- E. When one stress test indicates a high likelihood of CAD and another stress test suggests a low likelihood (e.g., a patient 2.0 mm ST-segment depression and exercise hypotension with normal radionuclide myocardial perfusion imaging); and
- F. When one component of a stress imaging test exhibits high likelihood and another component of the same stress test exhibits low likelihood (i.e. the presence of the high-risk marker described as transient ischemic dilation (TID) of the ventricular cavity with stress can indicate the presence of high-risk coronary anatomy (Abidov, 2003)). However, TID can also occur for physiological reasons, such as a hypertensive response to stress (Smelley, 2007). Thus, patients with TID and normal perfusion portions of a myocardial perfusion SPECT scan are frequently subjected to invasive coronary angiography. This is most often a low-yield procedure, since severe and extensive disease only is present in about 13% of patients with normal or near-normal nuclear perfusion pattern and TID (Abidov, 2004).

The Societies note that screening asymptomatic patients with CCTA is inappropriate, and should not be performed as an initial diagnostic test. The proposed NCD, however, does not account for the clinical reality that non-invasive stress testing is commonly performed in asymptomatic individuals with multiple risk factors and that physicians may be called upon to guide management of asymptomatic patients with abnormal noninvasive tests. As prescribed in the comprehensive 2002 Stable Angina Guidelines (Gibbons, 2002), “The inclusion of asymptomatic patients with abnormal non-invasive tests does not constitute an endorsement of such tests for the purposes of screening but simply acknowledges the clinical reality that such patients often present for evaluation after such tests have been performed.”

Frequently, invasive coronary angiography is performed in these asymptomatic patients, in accordance with the following guidelines: Invasive coronary angiography received a Class IIa recommendation in “patients with an uncertain diagnosis after non-invasive testing in whom the benefit of a more certain diagnosis outweighs the risk and cost of coronary angiography (Gibbons, 2002) and patients who cannot undergo non-invasive [stress] testing because of disability, illness, or morbid obesity (Gibbons, 2002). Given the high likelihood of negativity of the invasive angiogram in these subjects, and the very high negative predictive value of CCTA, CCTA is highly useful in this population of individuals in order to preclude further invasive coronary artery evaluation. If coverage for CCTA were available in this situation, we believe the Medicare program would enjoy considerably lower future costs than those currently incurred.

3. Assessment of bypass graft location (e.g., internal mammary artery) prior to surgical intervention in patients undergoing repeat sternotomy. As repeat cardiac surgery carries with it substantial risk for potential injury to patent coronary artery grafts, the aorta or right ventricular structures, CCTA has been compared to standard of care imaging for patients

undergoing re-operation (Gasparovic, 2005). This study was not included in the proposed NCD, but it clearly demonstrates the superiority of CCTA compared to conventional invasive coronary angiography for defining the position of patent bypass grafts and other important structures in relationship to the sternum, thus reducing the morbidity of the re-operative procedure by surgical method modification.

4. Coronary artery evaluation in patients undergoing non-coronary cardiac surgery. Invasive coronary angiography is routinely performed in middle-aged or older patients prior to non-coronary cardiac surgery for valvular heart disease. The likelihood of significant coronary artery stenoses increases with age, and is more prevalent in patients undergoing surgery for degenerative or calcific aortic stenosis (over 50%) than in a younger person (Bruch, 2007, Aronow, 2007). Given the very high negative predictive value of CTA, patients could routinely undergo CTA instead of invasive angiography, and those with normal results could then proceed to surgery safely. Use of such a practice would thereby result in a marked reduction of the number of pre-operative invasive angiograms (as has been described but not evaluated by the proposed NCD).

The Societies again recommend that CMS consider these indications as “covered” when: either there is no alternative (as in scenarios 1 and 3 referenced above); or only as an invasive angiography alternative with low likelihood of required coronary artery intervention (scenarios 2 and 4 referenced above).

Definition of Populations Eligible for Coverage:

The proposed NCD defines two symptomatic patient populations who will be potentially eligible for coverage:

1. Symptomatic patients with chronic stable angina at intermediate risk of CAD; and
2. Symptomatic patients with unstable angina at a low risk of short-term death and intermediate risk of CAD.

These descriptions—both for chronic as well as unstable patients—do not accurately define the patient population for which CCTA, or any other non-invasive method, is most often employed:

- “*Chronic stable angina.*” The NCD describes potential eligibility for coverage of “symptomatic patients with chronic stable angina at intermediate risk of CAD.” In patients with a chronic presentation of suspected CAD, the term “chronic stable angina at intermediate risk of CAD” is not appropriate. In the 2007 Chronic Angina Focused Update of the ACC/AHA 2002 Guidelines for Management of Patients with Chronic Stable Angina, “chronic stable angina” is intended to apply to “adult patients with stable chest pain syndromes and known or suspected ischemic heart disease” as well as those with “ischemic equivalents,” (e.g., dyspnea on exertion or arm pain with exertion). Thus, instead of “chronic stable angina,” the correct reference should be to “chronic stable angina or anginal equivalent.”
- “*Intermediate risk of CAD.*” The NCD describes potential eligibility for coverage of “symptomatic patients with chronic stable angina at intermediate risk of CAD;” the proposed NCD states that the stratification of risk should be performed with the Framingham risk score (FRS). However, the National Cholesterol Education Program states clearly that the FRS “is designed to estimate risk in adults aged 20 and older who do not have heart disease or diabetes.” Thus, the Societies note that the FRS was never

intended to be applied in patients with symptoms. Instead, for symptomatic patients, the pre-test likelihood of angiographically significant CAD is uniformly employed by clinicians and guidelines, based on age, gender, risk factors, and symptoms, as initially suggested by Diamond and Forrester. As described in the ACC/AHA Guidelines on Stable Angina, the likelihood of CAD based upon Diamond and Forrester or Duke classifications (Pryor, 1993) serves as the starting point for the clinician in the evaluation of symptomatic patients—for stratification of patients into groups with low (<10%), intermediate (10-90%), and high (>90%) risk of obstructive CAD. (Stable Angina Guidelines 2002) It is well-documented that the greatest clinical and economic value of non-invasive coronary artery testing is achieved when it is used for symptomatic individuals with intermediate pre-test likelihood of angiographically-significant CAD.

Since the value of diagnostic testing is greatest in patients with an intermediate likelihood of disease, patients with an intermediate likelihood of CAD become excellent candidates for noninvasive imaging of any type, including CCTA. Therefore, instead of referring to “symptomatic patients with chronic stable angina at intermediate risk of CAD,” the correct terminology would be “symptomatic patients with chronic stable angina or anginal equivalent and an intermediate pre-test probability of CAD.” For further clarification, we would like to draw CMS’ attention to articles quoted from its own proposed NCD’s references:

- Snow, 2004—The Snow article does not address the reported topic; and
 - Keevil, 2007; Wilson, 1998—Both the Keevil and Wilson articles describe the use of FRS for asymptomatic patients. More appropriately, the Societies would suggest use of the ACC/AHA Stable Angina Guidelines and Unstable Angina Guidelines for incorporation of definitions with uniform agreement for individuals who would benefit most from CCTA.
- “Unstable angina.” The proposed NCD refers to “symptomatic patients with unstable angina at a low risk of short term death and intermediate risk of CAD.” In patients with an acute presentation of suspected CAD, the term “unstable angina” is not clinically appropriate. “Unstable angina” is now considered a subset of Acute Coronary Syndromes (Braunwald 2002), and implies that a diagnosis has already been made. The prevalence of patients who present to the emergency department or other setting with acute chest pain who are subsequently diagnosed with acute coronary syndromes is low, and it is this subset of patients who are “at a low risk of short term death and intermediate risk of CAD.” Owing to the extraordinarily high negative predictive value of CCTA, use of CCTA may be most beneficial for this population of patients. Thus, as with the previous examples above, any reference to “symptomatic patients with unstable angina at a low risk of short term death and intermediate risk of CAD,” should be replaced by “symptomatic patients with possible acute coronary syndrome (ACS), a low risk of short term death and an intermediate probability of CAD.”

Critique of Questions Asked by CMS for CED:

The Societies are deeply concerned that the primary practical result of this proposed NCD will be to severely limit access to CCTA for Medicare beneficiaries rather than produce any new evidence of substance that will help clinicians and policy-makers continue to define the most efficient uses of CCTA for diagnosing coronary artery disease. As noted above, numerous clinical trials have already established the usefulness of CCTA and justified its coverage as reasonable and necessary for

diagnosis of CAD in Medicare patients. We believe that any new evidence development must not be limited to academic research settings and randomized controlled trials, but should instead focus on questions that can be answered in the everyday clinical practice settings where Medicare patients receive most of their care.

The proposed NCD states that for a clinical study to qualify under CED, it must address one or more of three questions. Again, while we strongly believe that an NCD with CED is not appropriate at this time based on the sum of existing clinical evidence, in the event that CMS elects to proceed with this decision, there are numerous elements of these proposed questions that the Societies urge CMS to reconsider for purposes of making them more clinically appropriate. Without the following recommended changes, we fear that substantial waste of limited Medicare resources will be spent on a research endeavor that will produce little clinically useful information:

Question # 1: *Does cardiac CTA have the ability to diagnose or exclude coronary artery disease as well as invasive coronary angiography?*

- CCTA is a useful test for evaluation of individuals with suspected CAD based on its ability to diagnose and exclude coronary artery disease compared to invasive coronary angiography. CCTA has demonstrated excellent sensitivity, specificity, and negative predictive value as compared with invasive coronary angiography.
- Evaluation of the utility of CCTA should be performed by assessment of its clinical usefulness in individuals with suspected CAD, rather than by comparing its relative ability to diagnose or exclude CAD as well as invasive coronary angiography. Since the definition of CAD is by its very nature angiographic (>50% stenosis by invasive coronary angiography is the accepted gold standard), it is therefore—by design—impossible for any test to be as accurate as this “gold standard.”
- CCTA provides similar information to invasive coronary angiography, but also provides additional useful information that invasive coronary angiography cannot. CCTA permits visualization of the coronary artery lumen as well as the coronary artery wall, thus allowing visualization of plaque composition, plaque remodeling, and furthermore, diagnosis of coronary atherosclerosis that is not represented by invasive coronary angiography and other non-invasive coronary artery imaging tests. That these factors are associated with ischemia, development of acute coronary syndromes, and future cardiac death renders CCTA useful in a manner above and beyond percent diameter stenosis measured by invasive angiography.
- Modification to the above question into three separate questions could focus its intent and more precisely measure the ongoing impact of CCTA on clinical management; for example:
 - What is the impact of CCTA on the frequency of non-obstructive findings during invasive coronary angiography (ICA) when performed prior to ICA?
 - Does CCTA reliably identify patients eligible for revascularization?
 - What percentage of patients with non-high risk findings on CCTA proceeds to ICA?

Question #2: *Does coronary CTA reduce the need for invasive coronary angiography?*

- CCTA exhibits an excellent diagnostic performance for the detection and exclusion of significant CAD, and thus can be especially useful for diagnosis of patients with abnormal results from other non-invasive coronary artery tests. As such, CCTA should be evaluated in the context of both reduction of need for invasive coronary angiography as well as appropriateness of referral. Appropriate referral of patients with abnormal non-invasive coronary artery tests is indicated and beneficial. In this regard, CCTA substantially reduces the rate of invasive coronary angiography in patients with abnormal stress tests.
- As it is well-established that coronary artery stenoses of <25% of the coronary diameter are common in patients with intermediate likelihood of CAD, and in clinical practice such patients are not referred to coronary angiography. CCTA test performance therefore, as assessed by its negative predictive value, is of import here. CCTA possesses a high negative predictive value in all patient populations studied to date, and exhibits a higher negative predictive value than any other non-invasive coronary artery test.
- Therefore, given its high negative predictive value, CCTA is useful in patients in whom invasive coronary angiography is routinely performed, but the likelihood of coronary artery intervention is low. Such subsets include patients prior to non-coronary cardiac surgery or non-cardiac surgery or patients with discordant non-invasive coronary artery test results (e.g., discordance between the stress electrocardiogram and the stress cardiac imaging).

Question #3: *Does coronary CTA improve health outcomes for patients with acute chest pain who present in the emergency room or other setting?*

- CCTA is a non-invasive diagnostic test, not a therapeutic intervention. No diagnostic test (including CCTA) is capable of directly improving health outcomes. Instead, CCTA should prompt appropriate therapies which, if properly instituted, can then favorably affect health outcomes.
- We believe that the most appropriate questions and metrics of CCTA's impact on clinical management should include, in addition to diagnostic test characteristics and performance measures (Question #1), and reduction of unnecessary invasive coronary angiograms (Question #2):
 - What is the impact of CCTA on CAD-related medication administration and compliance?
 - Does CCTA reduce rates of invasive procedure-related complications?

These changes should become evident without amplification of adverse cardiovascular events, cumulative radiation dose and health-care costs.

The current LCD status of CCTA use in diagnosis of CAD has fostered the development of groundbreaking clinical trial research and data collection to answer ongoing questions about the utility of CCTA. Maintaining the current LCD process would allow the CCTA community to continue exploring additional important clinical questions. Several medical societies are exploring registry models that would examine such questions by measuring the utilization of CCTA and its impact on clinical management. These efforts would build upon the already robust response of the CCTA community to take responsibility for demonstrating the utility of this new technology, and would

also go beyond just making comparisons to the current “gold standard” of ICA. The proposed NCD will only slow the development of evidence by academia, societies and registries rather than accelerate it.

Conclusion:

The scientific data supporting the clinical utility of CCTA has already rapidly accrued, and continues to accumulate. As discussed above, many studies evaluating the clinical utility of 64-slice CCTA were not included for review by CMS in the proposed NCD—thereby precluding comprehensive assessment of CCTA for eligibility of coverage. We strongly urge CMS to consider the entirety of available published evidence before limiting needed access of this clinically useful technology to Medicare beneficiaries.

In a variety of both academic and non-academic settings, CCTA has been demonstrated to be the most accurate non-invasive coronary artery test for the identification and exclusion of significant CAD. This high diagnostic performance has been proven in a large number of patients with differing pre-test CAD risk and CAD prevalence. As such, clinical CCTA has been endorsed by the professional societies in appropriateness, consensus, and scientific statements, as well as for a variety of indications, including those to be considered eligible only for CED reimbursement in the proposed NCD. We encourage CMS to bear in mind the clinical indications agreed upon by expert consensus of the professional societies in order not to limit the substantial breadth of clinical utility that CCTA may provide to Medicare beneficiaries.

Further, the descriptions of those Medicare beneficiaries who would be eligible for coverage with evidence development in the proposed NCD do not accurately define the patient population for which CCTA, or any other non-invasive coronary artery test, is most often employed. Barring abandonment of the CED designation in the final NCD, CMS must at least modify the descriptions of potentially eligible Medicare beneficiaries with chronic stable angina or anginal equivalent and with possible acute coronary syndrome with a low risk of short term death and low to intermediate likelihood of CAD.

The Societies believe that ongoing assessment of efficacy outcomes for diagnostic testing should be conducted, as it should be with all clinical practices and treatments generally where possible, but such evaluations must be done through different means than those associated with the assessment of therapeutic interventions out of acknowledgment for the uniqueness of each type of modality. Again, the Societies strongly recommend against initiating a CED policy with respect to coverage of CCTA used in the diagnosis of CAD. However, should CMS elect to implement a CED, we emphatically urge the agency to fully evaluate the Societies’ concerns regarding the questions asked by the proposed CED requirements, and to consider alternative questions not asked in the draft policy.

Again, non-coverage of CCTA, or coverage under the conditions provided in the proposed CED runs contrary to the coverage decisions established through LCDs in all 50 states and the District of Columbia. Implementation of the NCD as proposed will limit access to CCTA for Medicare beneficiaries who would benefit significantly from CCTA. The Societies encourage CMS to retain the LCDs in lieu of an NCD with CED.

Professional societies are cognizant of the challenges that advances in imaging may pose in light of the ever-increasing health care delivery costs faced by the Medicare program and private plans as

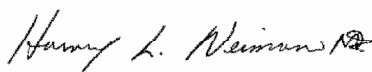
well. We have been consistent in our commitment to the development of scientific evidence assessing new technology, as is evidenced by our members' production of many of the manuscripts referenced by CMS in the proposed NCD, and the additional ones referred to by the Societies in this letter. Further, professional societies recognize our critical role in aiding CMS, payors and the general healthcare community in understanding the best application of these important technologies. Our work developing Appropriateness Criteria and projects to promote their implementation in the practice setting, along with our society-led development of data registries under ACRIN and NCDR leadership to further promote imaging quality for purposes of determining and promoting both efficient and cost-effective care continues to demonstrate our commitment to addressing payors' needs for assistance in these regards.

The Societies thank you again for the opportunity to review the proposed NCD. We are eager to work with CMS to determine the most appropriate Medicare coverage policy for CCTA, and would welcome the opportunity to engage in a dialogue with the agency about how the Medicare program might help to facilitate further research on CCTA. Please contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 202-375-6398 or rkelly@acc.org or Anita Pennington, ACR's Health Policy Analyst at 703- 648-8900, ext. 4923 or apennington@acr.org with any questions.

Sincerely,



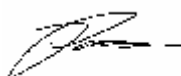
James T. Dove, M.D., F.A.C.C.
President
American College of Cardiology




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



William A. Van Decker, M.D.
President
American Society of Nuclear Cardiology



Pamela K. Woodard, M.D.
President
North American Society for
Cardiovascular Imaging



Bonnie Weiner, M.D.
President
Society for Cardiovascular Angiography and
Interventions



Michael Poon, M.D.
President
Society for Cardiovascular Computed
Tomography

CC: Mr. Kerry Weems
Mr. Herb Kuhn
Jack Lewin, M.D. C.E.O.

APPENDIX -- REFERENCES

Evidence Not Evaluated in the Proposed Decision Memo:

Table 1 – 40 and 64 slice studies with angiographic correlation not referenced in the proposed NCD. Invasive angiography used as the reference standard.					
Author (reference)	Year	Number	Sensitivity (%)	Specificity (%)	Negative predictive power (%)
Raff	2005	70	86	95	98
Meijboom	2007	402	99	85	99
Leber †	2007	90	95	90	98
Pundziute	2007	103	97	91	98
Herzog	2007	55	100	83	100
Meijboom	2007	254	98	86	98
Cademartiri	2007	72	100	98	100
Scheffel	2007	50	100	95	100
Leschka	2005	67	94	97	99
Ghostine	2006	66	95	97	97
Shabestari	2007	143	94	94	97
Hausleiter	2007	243	99	75	99
Muhlenbruch	2007	51	98	50	75
Andreini *	2007	200	99	96	100
Pugliese	2006	35	99	96	99
Watkins **	2007	85	86	97	97
Mollet	2005	52	99	95	99
Busch	2007	25	89	100	100
Johnson †	2007	35	100	89	100
Leschka †	2007	74	98	87	97
Brodoefel	2007	102	91	99	98
Cademartiri	2007	170	96	98	98
Pontone	2007	120	86	91	100
Ropers †	2007	100	96	86	89
* <i>Found to be significantly safer than Invasive angiography (P<0.001)</i>					
** <i>40-slice system</i>					
† <i>Dual Source CT</i>					

Andreini D, Pontone G, Pepi M, Ballerini G, Bartorelli AL, Magini A, Quaglia C, Nobili E, Agostoni P. Diagnostic accuracy of multidetector computed tomography coronary angiography in patients with dilated cardiomyopathy. J Am Coll Cardiol. 2007;49:2044-50.

Busch S, Johnson TR, Nikolaou K, von Ziegler F, Knez A, Reiser MF, Becker CR. Visual and automatic grading of coronary artery stenoses with 64-slice CT angiography in reference to invasive angiography. Eur Radiol. 2007;17:1445-51.

Brodoefel H, Reimann A, Burgstahler C, Schumacher F, Herberts T, Tsiflikas I, Schroeder S, Claussen CD, Kopp AF, Heuschmid M. Noninvasive coronary angiography using 64-slice spiral computed tomography in an unselected patient collective: Effect of heart rate, heart rate variability and coronary calcifications on image quality and diagnostic accuracy. Eur J Radiol. 2007 Jun 26; [Epub ahead of print].

Cademartiri F, Maffei E, Palumbo A, Malagò R, Alberghina F, Aldrovandi A, Brambilla V, Runza G, La Grutta L, Menozzi A, Vignali L, Casolo G, Midiri M, Mollet NR. Diagnostic accuracy of 64-slice computed tomography coronary angiography in patients with low-to-intermediate risk. *Radiol Med (Torino)*. 2007;112:969-81.

Cademartiri F, Maffei E, Palumbo AA, Malagò R, La Grutta L, Meijboom WB, Aldrovandi A, Fusaro M, Vignali L, Menozzi A, Brambilla V, Coruzzi P, Midiri M, Kirchin MA, Mollet NR. Influence of intra-coronary enhancement on diagnostic accuracy with 64-slice CT coronary angiography. *Eur Radiol*. 2007 Oct 13; [Epub ahead of print].

Ghostine S, Caussin C, Daoud B, Habis M, Perrier E, Pesenti-Rossi D, Sigal-Cinqualbre A, Angel CY, Lancelin B, Capderou A, Paul JF. Non-invasive detection of coronary artery disease in patients with left bundle branch block using 64-slice computed tomography. *J Am Coll Cardiol*. 2006;48:1929-34.

Hausleiter J, Meyer T, Hadamitzky M, Zankl M, Gerein P, Dörrler K, Kastrati A, Martinoff S, Schömig A. Non-invasive coronary computed tomographic angiography for patients with suspected coronary artery disease: the Coronary Angiography by Computed Tomography with the Use of a Submillimeter resolution (CACTUS) trial. *Eur Heart J*. 2007;28:3034-41.

Herzog C, Zwerner PL, Doll JR, Nielsen CD, Nguyen SA, Savino G, Vogl TJ, Costello P, Schoepf UJ. Significant coronary artery stenosis: comparison on per-patient and per-vessel or per-segment basis at 64-section CT angiography. *Radiology*. 2007;244:112-20.

Johnson TR, Nikolaou K, Busch S, Leber AW, Becker A, Wintersperger BJ, Rist C, Knez A, Reiser MF, Becker CR. Diagnostic accuracy of dual-source computed tomography in the diagnosis of coronary artery disease. *Invest Radiol*. 2007;42:684-91

Leber AW, Johnson T, Becker A, von Ziegler F, Tittus J, Nikolaou K, Reiser M, Steinbeck G, Becker CR, Knez A. Diagnostic accuracy of dual-source multi-slice CT-coronary angiography in patients with an intermediate pretest likelihood for coronary artery disease. *Eur Heart J*. 2007;28:2354-60.

Leschka S, Alkadhi H, Plass A, Desbiolles L, Grünenfelder J, Marincek B, Wildermuth S. Accuracy of MSCT coronary angiography with 64-slice technology: first experience. *Eur Heart J*. 2005;26:1482-7.

Leschka S, Scheffel H, Desbiolles L, Plass A, Gaemperli O, Stolzmann P, Genoni M, Luescher T, Marincek B, Kaufmann PA, Alkadhi H. Combining Dual-Source Computed Tomography Coronary Angiography and Calcium Scoring: Added Value for the Assessment of Coronary Artery Disease. *Heart*. 2007 Nov 21; [Epub ahead of print].

Meijboom WB, van Mieghem CA, Mollet NR, Pugliese F, Weustink AC, van Pelt N, Cademartiri F, Nieman K, Boersma E, de Jaegere P, Krestin GP, de Feyter PJ. 64-slice computed tomography coronary angiography in patients with high, intermediate, or low pretest probability of significant coronary artery disease. *J Am Coll Cardiol*. 2007;50:1469-75.

Meijboom WB, Weustink AC, Pugliese F, van Mieghem CA, Mollet NR, van Pelt N, Cademartiri F, Nieman K, Vourvouri E, Regar E, Krestin GP, de Feyter PJ. Comparison of diagnostic accuracy of 64-slice computed tomography coronary angiography in women versus men with angina pectoris. *Am J Cardiol*. 2007;100:1532-7.

Mollet NR, Cademartiri F, van Mieghem CA, Runza G, McFadden EP, Baks T, Serruys PW, Krestin GP, de Feyter PJ. High-resolution spiral computed tomography coronary angiography in patients referred for diagnostic conventional coronary angiography. *Circulation*. 2005;112:2318-23.

Mühlenbruch G, Seyfarth T, Soo CS, Pregalathan N, Mahnken AH. Diagnostic value of 64-slice multi-detector row cardiac CTA in symptomatic patients. *Eur Radiol.* 2007;17:603-9.

Pontone G, Andreini D, Quaglia C, Ballerini G, Nobili E, Pepi M. Accuracy of multidetector spiral computed tomography in detecting significant coronary stenosis in patient populations with differing pre-test probabilities of disease. *Clin Radiol.* 2007;62:978-85.

Pugliese F, Mollet NR, Runza G, van Mieghem C, Meijboom WB, Malagutti P, Baks T, Krestin GP, deFeyter PJ, Cademartiri F. Diagnostic accuracy of non-invasive 64-slice CT coronary angiography in patients with stable angina pectoris. *Eur Radiol.* 2006;16:575-82.

Pundziute G, Schuijf JD, Jukema JW, van Werkhoven JM, Boersma E, de Roos A, van der Wall EE, Bax JJ. Gender Influence on the Diagnostic Accuracy of 64-Slice Multislice Computed Tomography Coronary Angiography for Detection of Obstructive Coronary Artery Disease. *Heart*, 2008;94:48-52.

Raff GL, Gallagher MJ, O'Neill WW, Goldstein JA. Diagnostic accuracy of noninvasive coronary angiography using 64-slice spiral computed tomography. *J Am Coll Cardiol.* 2005;46:552-7.

Ropers U, Ropers D, Pflederer T, et al. Influence of Heart Rate on the Diagnostic Accuracy of Dual-Source Computed Tomography Coronary Angiography *J Am Coll Cardiol* 2007;50: 2393-2398.

Scheffel H, Leschka S, Plass A, Vachenaer R, Gaemperli O, Garzoli E, Genoni M, Marincek B, Kaufmann P, Alkadhi H. Accuracy of 64-slice computed tomography for the preoperative detection of coronary artery disease in patients with chronic aortic regurgitation. *Am J Cardiol.* 2007;100:701-6.

Shabestari AA, Abdi S, Akhlaghpour S, Azadi M, Baharjoo H, Pajouh MD, Emami Z, Esfahani F, Firouzi I, Hashemian M, Kouhi M, Mozafari M, Nazeri I, Roshani M, Salevatipour B, Tavalla H, Tehrai M, Zarrabi A. Diagnostic performance of 64-channel multislice computed tomography in assessment of significant coronary artery disease in symptomatic subjects. *Am J Cardiol.* 2007;99:1656-61.

Watkins MW, Hesse B, Green CE, Greenberg NL, Manning M, Chaudhry E, Dauerman HL, Garcia MJ. Detection of coronary artery stenosis using 40-channel computed tomography with multi-segment reconstruction. *Am J Cardiol.* 2007;99:175-81.

Existing Statements Defining Appropriateness of CCTA:

Hendel RC, Patel MR, Kramer CM, Poon M. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR 2006 appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging: a report of the American College of Cardiology Foundation/American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. *J Am Coll Cardiol* 2006;48:1475–97.”

Budoff MJ, Achenbach S, Blumenthal RS, Carr JJ, Goldin JG, Greenland P, Guerci AD, Lima JA, Rader DJ, Rubin GD, Shaw LJ, Wieggers SE; American Heart Association Committee on Cardiovascular Imaging and Intervention; American Heart Association Council on Cardiovascular Radiology and Intervention; American Heart Association Committee on Cardiac Imaging, Council on Clinical Cardiology. 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;114:1761-91.

Hendel RC, Patel MR, Kramer CM, Poon M, Hendel RC, Carr JC, Gerstad NA, Gillam LD, Hodgson JM, Kim RJ, Kramer CM, Lesser JR, Martin ET, Messer JV, Redberg RF, Rubin GD, Rumsfeld JS, Taylor AJ, Weigold WG, Woodard PK, Brindis RG, Hendel RC, Douglas PS, Peterson ED, Wolk MJ, Allen JM, Patel MR; American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group; American College of Radiology; Society of Cardiovascular Computed Tomography; Society for Cardiovascular Magnetic Resonance; American Society of Nuclear Cardiology; North American Society for Cardiac Imaging; Society for Cardiovascular Angiography and Interventions; Society of Interventional Radiology. *J Am Coll Cardiol*. 2006 Oct 3;48(7):1475-97.

Poon M, Rubin GD, Achenbach S, Attebery TW, Berman DS, Brady TJ, Jacobs JE, Hecht HS, Lima JA, Weigold WG. Consensus update on the appropriate usage of cardiac computed tomographic angiography. *J Invasive Cardiol*. 2007;19:484-90.

Stillman AE, Oudkerk M, Ackerman M, Becker CR, Buszman PE, de Feyter PJ, Hoffmann U, Keadey MT, Marano R, Lipton MJ, Raff GL, Reddy GP, Rees MR, Rubin GD, Schoepf UJ, Tarulli G, van Beek EJ, Wexler L, White CS. Use of multidetector computed tomography for the assessment of acute chest pain: a consensus statement of the North American Society of Cardiac Imaging and the European Society of Cardiac Radiology. *Eur Radiol*. 2007;17:2196-207.

Clinically-Valuable Indications of CCTA Excluded from Proposed Coverage:

Abidov A, Bax JJ, Hayes SW, Cohen I, Nishina H, Yoda S, Kang X, Aboul-Enein F, Gerlach J, Friedman JD, Hachamovitch R, Germano G, Berman DS. Integration of automatically measured transient ischemic dilation ratio into interpretation of adenosine stress myocardial perfusion SPECT for detection of severe and extensive CAD. *J Nucl Med.* 2004;45:1999-2007.

Abidov A, Bax JJ, Hayes SW, Hachamovitch R, Cohen I, Gerlach J, Kang X, Friedman JD, Germano G, Berman DS. Transient ischemic dilation ratio of the left ventricle is a significant predictor of future cardiac events in patients with otherwise normal myocardial perfusion SPECT. *J Am Coll Cardiol.* 2003;42:1818-25.

Aronow WS. Valvular aortic stenosis in the elderly. *Cardiol Rev.* 2007;15:217-25.

Bruch C, Kauling D, Reinecke H, Rothenburger M, Scheld HH, Breithardt G, Wichter T. Prevalence and prognostic impact of comorbidities in patients with severe aortic valve stenosis. *Clin Res Cardiol.* 2007;96:23-9.

Gasparovic H, Rybicki FJ, Millstine J, Unic D, Byrne JG, Yucel K, Mihaljevic T. Three dimensional computed tomographic imaging in planning the surgical approach for redo cardiac surgery after coronary revascularization. *Eur J Cardiothorac Surg.* 2005;28:244-9.

Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, Ferguson TB Jr, Fihn SD, Fraker TD Jr, Gardin JM, O'Rourke RA, Pasternak RC, Williams SV; American College of Cardiology; American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic Stable Angina). ACC/AHA 2002 guideline update for the management of patients with chronic stable angina--summary article: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic Stable Angina). *J Am Coll Cardiol.* 2003;41:159-68.

Hage FG, Dubovsky EV, Heo J, Iskandrian AE. Outcome of patients with adenosine-induced ST-segment depression but with normal perfusion on tomographic imaging. *Am J Cardiol.* 2006;98:1009-11.

Laissy JP, Messika-Zeitoun D, Serfaty JM, Sebban V, Schouman-Claeys E, Iung B, Vahanian A. Comprehensive evaluation of preoperative patients with aortic valve stenosis: usefulness of cardiac multidetector computed tomography. *Heart.* 2007;93:1121-5.

Mahenthiran J, Bangalore S, Yao SS, Chaudhry FA. Comparison of prognostic value of stress echocardiography versus stress electrocardiography in patients with suspected coronary artery disease. *Am J Cardiol.* 2005;96:628-34.

Pouleur AC, le Polain de Waroux JB, Kefer J, Pasquet A, Coche E, Vanoverschelde JL, Gerber BL. Usefulness of 40-slice multidetector row computed tomography to detect coronary disease in patients prior to cardiac valve surgery. *Eur Radiol.* 2007;17:3199-207

Reant P, Brunot S, Lafitte S, Serri K, Leroux L, Corneloup O, Iriart X, Coste P, Dos Santos P, Roudaut R, Laurent F. Predictive value of noninvasive coronary angiography with multidetector computed tomography to detect significant coronary stenosis before valve surgery. *Am J Cardiol.* 2006;97:1506-10.

Smelley MP, Virnich DE, Williams KA, Ward RP. A hypertensive response to exercise is associated with transient ischemic dilation on myocardial perfusion SPECT imaging. *J Nucl Cardiol.* 2007;14:537-43.

Definition of Populations Eligible for Coverage:

Braunwald E, Antman EM, Beasley JW, Califf RM, Cheitlin MD, Hochman JS, Jones RH, Kereiakes D, Kupersmith J, Levin TN, Pepine CJ, Schaeffer JW, Smith EE 3rd, Steward DE, Theroux P, Gibbons RJ, Alpert JS, Faxon DP, Fuster V, Gregoratos G, Hiratzka LF, Jacobs AK, Smith SC Jr; American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients With Unstable Angina). ACC/AHA guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction--2002: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients With Unstable Angina). *Circulation*. 2002;106:1893-900.

Diamond GA, Forrester JS. Analysis of probability as an aid in the clinical diagnosis of coronary-artery disease. *N Engl J Med* 1979;300:1350-1358.

Fraker TD Jr, Fihn SD; 2002 Chronic Stable Angina Writing Committee; American College of Cardiology; American Heart Association, Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, Ferguson TB Jr, Gardin JM, O'Rourke RA, Pasternak RC, Williams SV, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Halperin JL, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura R, Page RL, Riegel B, Tarkington LG, Yancy CW. 2007 chronic angina focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to develop the focused update of the 2002 guidelines for the management of patients with chronic stable angina. *J Am Coll Cardiol*. 2007 ;50:2264-74.

Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, Ferguson TB Jr, Fihn SD, Fraker TD Jr, Gardin JM, O'Rourke RA, Pasternak RC, Williams SV; American College of Cardiology; American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic Stable Angina). ACC/AHA 2002 guideline update for the management of patients with chronic stable angina--summary article: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic Stable Angina). *J Am Coll Cardiol*. 2003;41:159-68.

Pryor DB, Shaw L, McCants CB, et al. Value of the history and physical in identifying patients at increased risk for coronary artery disease. *Ann Intern Med* 1993;118:81-90.

Critique of Questions Asked by CMS for CED:

Achenbach S, Moselewski F, Ropers D, Ferencik M, Hoffmann U, MacNeill B, Pohle K, Baum U, Anders K, Jang IK, Daniel WG, Brady TJ. Detection of calcified and non-calcified coronary atherosclerotic plaque by contrast-enhanced, submillimeter multi-detector spiral computed tomography: a segment-based comparison with intravascular ultrasound. *Circulation* 2004;109:14–17.

Falk E, Shah PK, Fuster V. Coronary plaque disruption. *Circulation*. 1995;92:657-71.

Glagov S, Weisenberg E, Zarins CK, Stankunavicius R, Kolettis GJ. Compensatory enlargement of human atherosclerotic coronary arteries. *N Engl J Med*. 1987;316:1371-5.

Hunink MG, Kuntz KM, Fleischmann KE, et al. Non-invasive imaging for the diagnosis of coronary artery disease: Focusing the development of new diagnostic technology. *Ann Intern Med* 1999;131:673-680

Leber AW, Becker A, Knez A, von Ziegler F, Sirol M, Nikolaou K, Ohnesorge B, Fayad ZA, Becker CR, Reiser M, Steinbeck G, Boekstegers P. Accuracy of 64-slice computed tomography to classify and quantify plaque volumes in the proximal coronary system: a comparative study using intravascular ultrasound. *J Am Coll Cardiol* 2006;47:672–677.

Leber AW, Knez A, Becker A, Becker C, von Ziegler F, Nikolaou K, Rist C, Reiser M, White C, Steinbeck G, Boekstegers P. Accuracy of multi-detector spiral computed tomography in identifying and differentiating the composition of coronary atherosclerotic plaques: a comparative study with intracoronary ultrasound. *J Am Coll Cardiol* 2004;43:1241–1247.

Leber AW, Knez A, Becker A, Becker C, Reiser M, Steinbeck G, Boekstegers P. Visualising non-calcified coronary plaques by CT. *Int J Cardiovasc Imaging* 2005;21:55–61.

Leber AW, Knez A, von Ziegler F, Becker A, Nikolaou K, Paul S, Wintersperger B, Reiser M, Becker CR, Steinbeck G, Boekstegers P. Quantification of obstructive and non-obstructive coronary lesions by 64-slice computed tomography: a comparative study with quantitative coronary angiography and intravascular ultrasound. *J Am Coll Cardiol* 2005;46:147–154.

Leber AW, von Ziegler F, Becker A, Becker CR, Reiser M, Steinbeck G, Knez A, Boekstegers P. Characteristics of coronary plaques before angiographic progression determined by Multi-Slice CT. *Int J Cardiovasc Imaging*. 2007 Nov 8; [Epub ahead of print].

Mushlin AI, Ruchlin HS, Callahan MA. Cost-effectiveness of diagnostic tests. *Lancet* 2001;358:1353-5

Rasouli ML, Shavelle DM, French WJ, McKay CR, Budoff MJ. Assessment of coronary plaque morphology by contrast-enhanced computed tomographic angiography: comparison with intravascular ultrasound. *Coron Artery Dis*. 2006;17:359-64.

Shaw LJ, Callister TQ, Raggi P. Establishing cost-effective thresholds for coronary disease screening: A predictive model with risk factors and coronary calcium. *Circulation* 2001;104:II-478

Topol EJ, Nissen SE. Our preoccupation with coronary luminology: the dissociation between clinical and angiographic findings in ischemic heart disease. *Circulation* 1995;92:2333–42.

Tuzcu EM, Kapadia SR, Tutar E, Ziada KM, Hobbs RE, McCarthy PM, Young JB, Nissen SE. High prevalence of coronary atherosclerosis in asymptomatic teenagers and young adults: evidence from intravascular ultrasound. *Circulation*. 2001;103:2705-10.

White CW, Wright CB, Doty DB, Hiratza LF, Eastham CL, Harrison DG, Marcus ML. Does visual interpretation of the coronary arteriogram predict the physiologic importance of a coronary stenosis? N Engl J Med. 1984;310:819-24.

Questions Not Considered by the Proposed NCD:

Budoff MJ, Rasouli ML, Shavelle DM, Gopal A, Gul KM, Mao SS, Liu SH, McKay CR. Cardiac CT Angiography (CTA) and Nuclear Myocardial Perfusion Imaging (MPI)-A Comparison in Detecting Significant Coronary Artery Disease. *Acad Radiol.* 2007;14:252-7.

Danciu SC, Herrera CJ, Stecy PJ, Carell E, Saltiel F, Hines JL. Usefulness of multislice computed tomographic coronary angiography to identify patients with abnormal myocardial perfusion stress in whom diagnostic catheterization may be safely avoided. *Am J Cardiol.* 2007;100:1605-8.

Gallagher MJ, Ross MA, Raff GL, Goldstein JA, O'Neill WW, O'Neil B. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. *Ann Emerg Med.* 2007;49:125-36.

Gilard M, Le Gal G, Cornily JC, Vinsonneau U, Joret C, Pennec PY, Mansourati J, Bosch J. Midterm prognosis of patients with suspected coronary artery disease and normal multislice computed tomographic findings: a prospective management outcome study. *Arch Intern Med.* 2007;167:1686-9.

Lesser JR, Flygenring B, Knickelbine T, Hara H, Henry J, Kalil A, Pelak K, Lindberg J, Pelzel J, Schwartz RS. Clinical utility of coronary CT angiography: coronary stenosis detection and prognosis in ambulatory patients. *Catheter Cardiovasc Interv.* 2007;69:64-72.

Lin F, Shaw LJ, Berman DS, Callister TQ, Weinsaft JW, Wong FJ, Szulc M, Tandon V, Okin PM, Devereux RB, Min JK. Multidetector computed tomography coronary artery plaque predictors of stress-induced myocardial ischemia by SPECT. *Atherosclerosis.* 2007 Aug 24; [Epub ahead of print]

Min JK, Shaw LJ, Devereux RB, Okin PM, Weinsaft JW, Russo DJ, Lippolis NJ, Berman DS, Callister TQ. Prognostic value of multidetector coronary computed tomographic angiography for prediction of all-cause mortality. *J Am Coll Cardiol.* 2007;50:1161-70.

Pundziute G, Schuijf JD, Jukema JW, Boersma E, de Roos A, van der Wall EE, Bax JJ. Prognostic value of multislice computed tomography coronary angiography in patients with known or suspected coronary artery disease. *J Am Coll Cardiol.* 2007;49:62-70.

Schuijf JD, Wijns W, Jukema JW, Atsma DE, de Roos A, Lamb HJ, Stokkel MP, Dibbets-Schneider P, Decramer I, De Bondt P, van der Wall EE, Vanhoenacker PK, Bax JJ. Relationship between noninvasive coronary angiography with multi-slice computed tomography and myocardial perfusion imaging. *J Am Coll Cardiol.* 2006;48:2508-14.

Rubinshtein R, Halon DA, Gaspar T, Jaffe R, Goldstein J, Karkabi B, Flugelman MY, Kogan A, Shapira R, Peled N, Lewis BS. Impact of 64-slice cardiac computed tomographic angiography on clinical decision-making in emergency department patients with chest pain of possible myocardial ischemic origin. *Am J Cardiol.* 2007;100:1522-6.

Omitted References for the use of CCTA in the Emergency Setting:

Sato Y, Matsumoto N, Ichikawa M, et al. Efficacy of multislice computed tomography for the detection of acute coronary syndrome in the emergency department. *Circ J* 2005;69:1047–1051.

White CS, Kuo D, Kelemen M, et al. Chest pain evaluation in the emergency department: Can MDCT provide a comprehensive evaluation? *AJR Am J Roentgenol* 2005;185:533–540.

Hoffmann U, Penal AJ, Ferencik M et al. MDCT in Early Triage of Patients with Acute Chest Pain *AJR Am J Roentgenol* 2006;187:1240–1247.

Hoffmann U, Nagurney JT, Moselewski F, et al. Coronary multidetector computed tomography in the assessment of patients with acute chest pain. *Circulation* 2006;114:2251–2260.

Meijboom WB, Mollet NR, Van Mieghem CA, Weustink AC, Pugliese F, van Pelt N, Cademartiri F, Vourvouri E, de Jaegere P, Krestin GP, de Feyter PJ. 64-Slice CT coronary angiography in patients with non-ST elevation acute coronary syndrome. *Heart*. 2007;93:1386-92.

Gallagher MJ, Ross MA, Raff GL, et al. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. *Ann Emerg Med* 2007;49:125–136.

Rubinshtein R, Halon DA, Gaspar T, et al. Usefulness of 64- slice cardiac computed tomographic angiography for diagnosing acute coronary syndromes and predicting clinical outcome in emergency department patients with chest pain of uncertain origin. *Circulation* 2007;115:1762–1768.

Hollander JE, Litt HI, Chase M, et al. Computed Tomography Coronary Angiography for Rapid Disposition of Low-risk Emergency Department Patients with Chest Pain Syndromes. *Acad Emerg Med* 2007;14:112-116.

Johnson TRC, Nikolaou K, Wintersperger BJ, et al. ECG-Gated 64-MDCT Angiography in the Differential Diagnosis of Acute Chest Pain. *AJR Am J Roentgen*. 2007;188:76-82

Goldstein JA, Gallagher MJ, O'Neill WW, et al. A randomized controlled trial of multi-slice coronary computed tomography for evaluation of acute chest pain patients. *J Am Coll Cardiol*. 2007;49:863–871.

Vrachliotis TG, Bis KG, Haidary A, et al. Atypical chest pain : Coronary, aortic, and pulmonary vasculature enhancement at biphasic singleinjection 64-section CT angiography. *Radiology* 2007;243:368–376.

Onuma K, Tanabe, Nakazawa G, et al. Non cardiac findings in cardiac imaging with multidetector computed tomography. *J Am Coll Cardiol* 2006;48:402–406.