**Baldwin, JoAnna F. (CMS/OCSQ)**

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 8:53 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Computed Tomographic Angiography (CAG-00385N)

---

**From:** Angela Mehle [mailto:amehle@RockyMountainHeart.com]
**Sent:** Thursday, January 10, 2008 3:18 PM
**To:** CMS CAGInquiries
**Subject:** Computed Tomographic Angiography (CAG-00385N)

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.

(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.

(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.

(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.

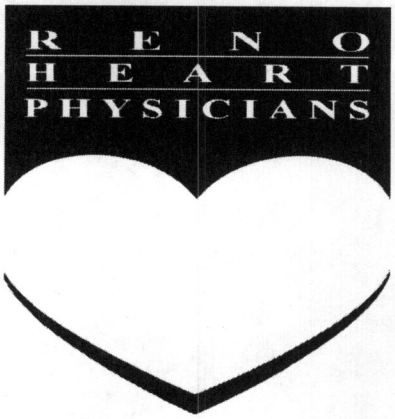
(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.

(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,
Dr. Gary W Hahn
Rocky Mountain Heart Associates, P.C.




(electronic submission)

**RE: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

I represent Reno Heart Physicians, which provides Cardiology services to the greater Reno/Northern Nevada area. We have 20 physicians, 112 employees and serve approximately 28,000 patients annually. Reno Heart Physicians appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Reno Heart Physicians believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Reno Heart Physicians strongly opposes Medicare's proposed decision for numerous reasons:

1. **CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization.** A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Reno Heart Physicians defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of Radiology (ACR), which

cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate from the authors'.

These currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patients with indeterminate stress tests or with stress tests whose findings are discrepant with the clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

Clinical trials currently underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

2. **CMS should rely on its local carriers' judgment and expertise put forth via Local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase.** CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to imaging procedures are made by local Medicare carriers, which work with specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LCD created jointly by the ACC and the ACR. Numerous third party payers, including Hometown Health Plan, Noridian, St. Mary's Health First, Aetna, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, HCSC, Wellmark and Excellus also provide coverage for CCTA for their beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCD's were based includes

clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

3. **In the covered clinical trial requirements outlined in the Proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for diagnosis should demonstrate improved patient health outcomes.**

   Reno Heart Physicians appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new *therapeutic* modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of this response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

   The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

4. **There are errors in the way CMS defined populations in its proposed indications for CT research protocols.** CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

   Chronic stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute

chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

"Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its likelihood *precedes* the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Reno Heart Physicians is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

5. **The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologists, who currently perform a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.**

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote far greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

6. **Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD,** especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks

inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

7. **Several recent studies, as well as empirical data from Reno Heart Physicians, demonstrate that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort.** Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

In closing, Reno Heart Physicians respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower-risk technology.
- Eliminate implementation of its proposed CED. Reno Heart Physicians recommends that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact on the delivery of appropriate care to beneficiaries. There are several excellent CCTA registries already in existence that may be used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in the development of these important quality endeavors, and
- Reno Heart Physicians fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Reno Heart Physicians appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me at (775) 327-8196 or via email at davedevalk@renoheart.com if you have any questions.

Sincerely,

David DeValk
CEO

## Baldwin, JoAnna F. (CMS/OCSQ)

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 9:00 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Computed Tomographic Angiography (CAG-00385N

---

**From:** Shelley Davis [mailto:sdavis@RockyMountainHeart.com]
**Sent:** Thursday, January 10, 2008 4:04 PM
**To:** CAGinquiries@cms.hhs.gov.
**Subject:** Computed Tomographic Angiography (CAG-00385N

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.

(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.

(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.

(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.

(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.

(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,
Dr Timothy W Leavitt
Rocky Mountain Heart Associates, P.C.

**Baldwin, JoAnna F. (CMS/OCSQ)**

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 9:05 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: CMS PROPOSAL

---

**From:** Jerry Miklin [mailto:jmiklin@RockyMountainHeart.com]
**Sent:** Thursday, January 10, 2008 8:04 PM
**To:** CMS CAGInquiries
**Subject:** CMS PROPOSAL

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.

(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.

(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.

(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.

(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.

(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,

Jerry S. Miklin, M.D., FACC
Chief of Cardiac Services
Exempla Lutheran Hospital

**Baldwin, JoAnna F. (CMS/OCSQ)**

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 9:00 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Proposed National Coverage Determination Memo for CCTA, CAG-00385N

---

**From:** Gwynn Glasscock [mailto:gwynnsuperscan@yahoo.com]
**Sent:** Thursday, January 10, 2008 4:53 PM
**To:** CMS CAGInquiries
**Subject:** Proposed National Coverage Determination Memo for CCTA, CAG-00385N

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.
(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.
(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.
(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.
(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.
(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,

Gwynn L. Glasscock RT(R)
SuperSCAN Heart and Body Imaging
Suite 201
3800 Lutheran Pkwy
Wheat Ridge, CO 80033

**Baldwin, JoAnna F. (CMS/OCSQ)**

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 9:05 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Proposed NCD for CCTA, CAG-00385N

---

**From:** Doug and Susan Martel [mailto:dsmar100@msn.com]
**Sent:** Thursday, January 10, 2008 9:03 PM
**To:** CMS CAGInquiries
**Subject:** Proposed NCD for CCTA, CAG-00385N

---

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.

(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.

(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.

(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients

with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.

(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.

(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,

Douglas R. Martel, M.D.

**Baldwin, JoAnna F. (CMS/OCSQ)**

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 9:00 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)

---

**From:** Mary Jane Borg [mailto:mjborg@illinoisheart.com]
**Sent:** Thursday, January 10, 2008 4:20 PM
**To:** CMS CAGInquiries
**Subject:** Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)

**RE: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

We represent Illinois Heart and Vascular which provides Cardiology services to the greater Chicago land area. We have 27 physicians, 92 employees and serve approximately 24,000 patients annually. Illinois Heart and Vascular appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Illinois Heart and Vascular believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Illinois Heart and Vascular strongly opposes Medicare's proposed decision for numerous reasons:

1. **CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization.** A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Illinois Heart and Vascular defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of Radiology (ACR), which cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate from the authors'.

   These currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patients with indeterminate stress tests or with stress tests whose findings are discrepant with the clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test

indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

Clinical trials currently underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

2. **CMS should rely on its local carriers' judgment and expertise put forth via Local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase.** CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to imaging procedures are made by local Medicare carriers, which work with specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LCD created jointly by the ACC and the ACR. Numerous third party payers, including Aetna, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, HCSC, Wellmark and Excellus also provide coverage for CCTA for their beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCDs were based includes clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

3. **In the covered clinical trial requirements outlined in the Proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for diagnosis should demonstrate improved patient health outcomes.**

   Illinois Heart and Vascular appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new *therapeutic* modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of this response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

   The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

4. **There are errors in the way CMS defined populations in its proposed indications for CT research protocols.** CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

Chronic stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

"Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its likelihood *precedes* the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Illinois Heart and Vascular is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

5. **The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologists, who currently perform a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.**

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote far greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

6. **Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD,** especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

7. **Several recent studies, as well as empirical data from Illinois Heart and Vascular, demonstrate that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort.** Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in

the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

losing Illinois Heart and Vascular respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower-risk technology.
- Eliminate implementation of its proposed CED. Illinois Heart and Vascular recommends that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact on the delivery of appropriate care to beneficiaries. There are several excellent CCTA registries already in existence that may be used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in the development of these important quality endeavors, and Illinois Heart and Vascular fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Illinois Heart and Vascular appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me at 630-528-4370 or via email at mjborg@illinoisheart.com if you have any questions.

Sincerely,

Mary Jane Borg, RN, BSN

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 Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

We represent Cardiovascular Associates, Ltd., which provides Cardiology services to the greater Hampton Roads area. We have 22 physicians, 115 employees and serve approximately 10,000 patients annually. Cardiovascular Associates appreciates the opportunity to comment on the Centers for Medicare & Medicare Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Cardiovascular Associates believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Cardiovascular Associates strongly opposes Medicare's proposed decision for numerous reasons:

1. CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization. A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Cardiovascular Associates defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of Radiology (ACR), which cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved

societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate form the authors'.

The currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patient with indeterminate stress tests or with stress tests whose findings are discrepant with clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

Clinical trials underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

2. CMS should rely on its local carriers' judgment and expertise put forth via local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase. CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LDC created jointly by the ACC and the
   ACR. Numerous third party payers, including Aetna, Optima, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCDs were based includes clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

3. In the covered clinical trial requirements outlined in the proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for diagnosis should demonstrate improved patient health outcomes.

   Cardiovascular Associates appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new therapeutic modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of the response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

   The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

4. There are errors in the way CMS defined populations in its proposed indications for CT research protocols. CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

   Chronis stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

   "Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its

likelihood precedes the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Cardiovascular Associates is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

5. The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologist, who currently performs a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote for greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

6. Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD, especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

7. Several recent studies, as well as empirical data from Cardiovascular Associates, demonstrates that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort. Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

In closing, Cardiovascular Associates respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower risk technology.
- Eliminate implementation of its proposed CED. Cardiovascular Associates recommend that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact of the delivery of appropriate care to the beneficiaries. There are several excellent CCTA registries already existence that maybe used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in development of these important quality endeavors, and Cardiovascular Associates fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Cardiovascular Associates appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me a 757-499-2825 or via email at vdonlon@cval.org if you have any questions.

Sincerely,

Vince Donlon
Practice Administrator

# Oklahoma Heart Institute

Wayne N. Leimbach, Jr., MD
Robert C. Sonnenschein, MD
Robert E. Lynch, MD
James J. Nemec, MD
Gregory D. Johnsen, MD
Alan M. Kaneshige, MD
Ernest Pickering, DO
Edward T. Martin, MD
Roger D. Des Prez, MD
Rebecca L. Smith, MD
Raj H. Chandwaney, MD
David A. Sandler, MD
Frank J. Gaffney, MD
Michael J. Fogli, MD
Eric G. Auerbach, MD
Kambeez Berenji, MD
Robert L. Smith, Jr., MD
Craig S. Cameron, MD

*Endocrinology*
Christian S. Hanson, DO
Tobie L. Bresloff, MD
D. Erik Aspenson, MD
Kelly R. Flesner, MD

*Executive Director*
Steven M. Struttmann, CPA, CMPE

**Oklahoma Heart Institute**
*1265 South Utica Ave.*
*Tulsa, Oklahoma 74104*
*918.592.0999*
*FAX 918.592.1021*

**Oklahoma Heart Institute at South Pointe**
*9228 S. Mingo Road*
*Tulsa, Oklahoma 74133*
*918.592.0999*
*FAX 918.878.2499*

January 11, 2008

Centers for Medicare & Medicaid Services
CAGinquiries@cms.hhs.gov

**Regarding: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

I represent Oklahoma Heart Institute, which provides Cardiology and Endocrinology services to the greater Tulsa and Northeast Oklahoma area. We have 21 physicians, 8 mid-level providers, and 160 employees that render care for more than 46,000 patient visits annually. Oklahoma Heart Institute appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Oklahoma Heart Institute believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Oklahoma Heart Institute strongly opposes Medicare's proposed decision for numerous reasons:

1. **CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization.** A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Oklahoma Heart Institute defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of

2. Radiology (ACR), which cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate from the authors'.

   These currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patients with indeterminate stress tests or with stress tests whose findings are discrepant with the clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

   Clinical trials currently underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

3. **CMS should rely on its local carriers' judgment and expertise put forth via Local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase.** CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to imaging procedures are made by local Medicare carriers, which work with specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LCD created jointly by the ACC and the ACR. Numerous third party payers, including Aetna, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, HCSC, Wellmark and Excellus also provide coverage for CCTA for their beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCDs were based includes clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

4. **In the covered clinical trial requirements outlined in the Proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for**

**diagnosis should demonstrate improved patient health outcomes.**

Oklahoma Heart Institute appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new *therapeutic* modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of this response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

5. **There are errors in the way CMS defined populations in its proposed indications for CT research protocols.** CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

   Chronic stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

   "Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its likelihood *precedes* the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Oklahoma Heart Institute is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

6. **The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologists, who currently perform a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.**

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote far greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

7. **Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD,** especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

8. **Several recent studies, as well as empirical data from Oklahoma Heart Institute, demonstrate that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort.** Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

In closing, Oklahoma Heart Institute respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower-risk technology.

- Eliminate implementation of its proposed CED. Oklahoma Heart Institute recommends that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact on the delivery of appropriate care to beneficiaries. There are several excellent CCTA registries already in existence that may be used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in the development of these important quality endeavors, and Oklahoma Heart Institute fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Oklahoma Heart Institute appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me at 918 595 0235 or via email at desprez@oklahomaheart.com if you have any questions.

Sincerely,

Steve Struttmann, CPA, CMPE
Executive Director

# Oklahoma Heart Institute

Wayne N. Leimbach, Jr., MD
Robert C. Sonnenschein, MD
Robert E. Lynch, MD
James J. Nemec, MD
Gregory D. Johnsen, MD
Alan M. Kaneshige, MD
Ernest Pickering, DO
Edward T. Martin, MD
Roger D. Des Prez, MD
Rebecca L. Smith, MD
Raj H. Chandwaney, MD
David A. Sandler, MD
Frank J. Gaffney, MD
Michael J. Fogli, MD
Eric G. Auerbach, MD
Kambeez Berenji, MD
Robert L. Smith, Jr., MD
Craig S. Cameron, MD

*Endocrinology*
Christian S. Hanson, DO
Tobie L. Bresloff, MD
D. Erik Aspenson, MD
Kelly R. Flesner, MD

*Executive Director*
Steven M. Struttmann, CPA, CMPE

**Oklahoma Heart Institute**
*1265 South Utica Ave.*
*Tulsa, Oklahoma 74104*
*918.592.0999*
*FAX 918.592.1021*

**Oklahoma Heart Institute at South Pointe**
*9228 S. Mingo Road*
*Tulsa, Oklahoma 74133*
*918.592.0999*
*FAX 918.878.2499*

January 11, 2008

Centers for Medicare & Medicaid Services
CAGinquiries@cms.hhs.gov

**Regarding: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

I represent Oklahoma Heart Institute, which provides Cardiology and Endocrinology services to the greater Tulsa and Northeast Oklahoma area. We have 21 physicians, 8 mid-level providers, and 160 employees that render care for more than 46,000 patient visits annually. Oklahoma Heart Institute appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Oklahoma Heart Institute believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Oklahoma Heart Institute strongly opposes Medicare's proposed decision for numerous reasons:

1. **CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization.** A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Oklahoma Heart Institute defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of

2. Radiology (ACR), which cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate from the authors'.

   These currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patients with indeterminate stress tests or with stress tests whose findings are discrepant with the clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

   Clinical trials currently underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

3. **CMS should rely on its local carriers' judgment and expertise put forth via Local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase.** CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to imaging procedures are made by local Medicare carriers, which work with specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LCD created jointly by the ACC and the ACR. Numerous third party payers, including Aetna, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, HCSC, Wellmark and Excellus also provide coverage for CCTA for their beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCDs were based includes clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

4. **In the covered clinical trial requirements outlined in the Proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for**

**diagnosis should demonstrate improved patient health outcomes.**

Oklahoma Heart Institute appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new *therapeutic* modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of this response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

5. **There are errors in the way CMS defined populations in its proposed indications for CT research protocols.** CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

   Chronic stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

   "Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its likelihood *precedes* the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Oklahoma Heart Institute is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

6. **The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologists, who currently perform a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.**

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote far greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

7. **Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD,** especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

8. **Several recent studies, as well as empirical data from Oklahoma Heart Institute, demonstrate that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort.** Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

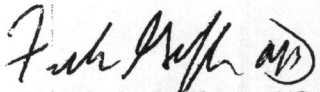
In closing, Oklahoma Heart Institute respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower-risk technology.

- Eliminate implementation of its proposed CED. Oklahoma Heart Institute recommends that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact on the delivery of appropriate care to beneficiaries. There are several excellent CCTA registries already in existence that may be used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in the development of these important quality endeavors, and Oklahoma Heart Institute fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Oklahoma Heart Institute appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me at 918 595 0235 or via email at cwilliams@oklahomaheart.com if you have any questions.

Sincerely,



Frank J. Gaffney, MD

# Oklahoma Heart Institute

Wayne N. Leimbach, Jr., MD
Robert C. Sonnenschein, MD
Robert E. Lynch, MD
James J. Nemec, MD
Gregory D. Johnsen, MD
Alan M. Kaneshige, MD
Ernest Pickering, DO
Edward T. Martin, MD
Roger D. Des Prez, MD
Rebecca L. Smith, MD
Raj H. Chandwaney, MD
David A. Sandler, MD
Frank J. Gaffney, MD
Michael J. Fogli, MD
Eric G. Auerbach, MD
Kambeez Berenji, MD
Robert L. Smith, Jr., MD
Craig S. Cameron, MD

*Endocrinology*
Christian S. Hanson, DO
Tobie L. Bresloff, MD
D. Erik Aspenson, MD
Kelly R. Flesner, MD

*Executive Director*
Steven M. Struttmann, CPA, CMPE

**Oklahoma Heart Institute**
*1265 South Utica Ave.*
*Tulsa, Oklahoma 74104*
*918.592.0999*
*FAX 918.592.1021*

**Oklahoma Heart Institute at South Pointe**
*9228 S. Mingo Road*
*Tulsa, Oklahoma 74133*
*918.592.0999*
*FAX 918.878.2499*

January 11, 2008

Centers for Medicare & Medicaid Services
CAGinquiries@cms.hhs.gov

**Regarding: Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)**

I represent Oklahoma Heart Institute, which provides Cardiology and Endocrinology services to the greater Tulsa and Northeast Oklahoma area. We have 21 physicians, 8 mid-level providers, and 160 employees that render care for more than 46,000 patient visits annually. Oklahoma Heart Institute appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for CTA (hereafter referred to as CCTA) for the diagnosis of Coronary Artery Disease (CAD) referenced above.

CMS, in its memo, proposes a narrowly defined Coverage with Evidence Development (CED) for CCTA for limited, inappropriately restrictive indications and strict research study protocols that must be submitted, reviewed and approved within 60 days of CMS' final decision. Oklahoma Heart Institute believes the proposed CED not only is extremely poor public policy but is precedent-setting in its attempt to utilize a reimbursement strategy for a diagnostic modality that mandates an assessment of its impact on health outcomes. Oklahoma Heart Institute strongly opposes Medicare's proposed decision for numerous reasons:

1. **CMS has failed to take into account a considerable body of current clinical, peer-reviewed evidence that demonstrates CCTA is a valuable technology to diagnose CAD that is less expensive and poses less risk to the patient than invasive cardiac catheterization.** A significant number of studies cited in CMS' proposed memo are based on older data that, not only do not reflect current clinical literature, but many of the cited studies used older technology (16-slice equipment). Oklahoma Heart Institute defers to the responses of the specialty clinical societies, namely the American College of Cardiology (ACC), Society of Cardiovascular Computed Tomography (SCCT) and the American College of

2. Radiology (ACR), which cite in detail the numerous clinical studies CMS did not consider in issuing the Proposed Decision Memo. Though the AHA Scientific Statement on the topic and the CCTA Appropriateness Criteria Document with input from all the involved societies (both published in 2006) are referenced in CMS' memo, the conclusions made by CMS are disparate from the authors'.

   These currently available studies and data demonstrate that CCTA, in specific patient populations, has a high sensitivity and specificity when compared to myocardial perfusion studies, treadmill stress testing and invasive cardiac catheterization in diagnosing the presence and extent of CAD. It has been evaluated in patients with symptomatic coronary disease, patients with coronary anomalies, and is particularly valuable in evaluating patients with indeterminate stress tests or with stress tests whose findings are discrepant with the clinical impression. When appropriately performed, CCTA often obviates the need for more invasive studies. This latter group is important as stress test indications include a number of presenting conditions other than chest discomfort (sudden death, atrial fibrillation, heart failure, etc).

   Clinical trials currently underway also hold great potential for continuing to affirm these conclusions as well as to assess the economic benefit of CCTA when compared to cardiac catheterization. To make a decision that drastically limits CCTA will inhibit clinicians' ability to gather the very data needed to prove CCTA's additional efficacy.

3. **CMS should rely on its local carriers' judgment and expertise put forth via Local Coverage Determinations (LCDs) in effect in all 50 states and keep the LCDs in place during its data-gathering phase.** CMS has granted its local Medicare contractors the authority to utilize clinical experts and specialty organizations in determining the appropriateness of local coverage decisions. The vast majority of coverage decisions with regard to imaging procedures are made by local Medicare carriers, which work with specialty societies and their own advisory committees to develop LCDs that support the use of CCTA to diagnose CAD.

   The LCDs include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA based on peer-reviewed clinical evidence and a comprehensive model LCD created jointly by the ACC and the ACR. Numerous third party payers, including Aetna, United Healthcare, Humana, Cigna, Wellpoint (14 states) and many Blue Cross Blue Shield carriers, most notably Highmark, HCSC, Wellmark and Excellus also provide coverage for CCTA for their beneficiaries based on clinical data, appropriateness criteria and accreditation guidelines.

   The Model LCD for CCTA upon which many LCDs were based includes clinical indications such as the evaluation of acute chest pain, equivocal stress tests, suspected congenital coronary anomalies, and for the detection of coronary artery disease in patients anticipating valve surgery, amongst others.

4. **In the covered clinical trial requirements outlined in the Proposed Decision Memo, CMS takes the unprecedented step of requiring that a technology used solely for**

**diagnosis should demonstrate improved patient health outcomes.**

Oklahoma Heart Institute appreciates the concept that positive clinical outcomes (both short term and long term) always should be the goal for the introduction of new *therapeutic* modalities. The difference between how we assess the impact of therapeutic vs. diagnostic modalities is beyond the scope of this response. However, an X-ray does not heal a broken bone; it merely reveals the break. Likewise, CCTA cannot treat a patient's CAD, it merely can diagnose it. CMS did not require clinical trials to demonstrate improved outcomes for a multitude of other technologies in use today. Therefore, CMS should not set an unrealistic precedent with regard to CCTA.

The proposed requirement to demonstrate that the use of a diagnostic imaging test will improve health outcomes will be impossible to achieve unless CCTA is applied in the community clinical setting with a realistic breadth of clinical presentations so a statistically relevant amount of long-term data can be collected and analyzed. Moreover, CMS effectively is eliminating that possibility by closing the door at the outset, limiting CCTA's application to an inappropriately narrow patient population and by so doing precluding the collection of long-term outcome data.

5. **There are errors in the way CMS defined populations in its proposed indications for CT research protocols.** CMS' two clinical diagnoses being proposed as the basis for reimbursement and study are "chronic stable angina at intermediate risk for CAD" and "unstable angina at low risk for death and with intermediate risk of CAD." These categories do not accurately reflect the defined patient populations upon which guidelines are currently based.

   Chronic stable angina pectoris implies the presence of CAD. A patient with chronic stable angina usually will have had some diagnostic test to support its presence (including potentially CCTA). For a patient with chronic stable angina whose symptoms are refractory to medicines, invasive cardiac catheterization usually is indicated. We are unaware of any guideline for chronic stable angina that stratifies that patient by "risk of CAD." Rather, guidelines for "acute chest pain" use risk of CAD for triage to certain tests or strategies. Indeed, it is the patient with acute chest pain of uncertain etiology where the presumed risk of CAD is used in decision-making and where CCTA has a potential role.

   "Unstable angina" or more commonly now "possible Acute Coronary Syndrome" likewise implies the presence of CAD as the assessment of its likelihood *precedes* the diagnosis. Most cardiologists refer patients with definite or presumed unstable angina for diagnostic catheterization, in part because of the ability to perform, when appropriate, percutaneous revascularization without the duplication, expense, added contrast and added risk of two or three separate procedures. As was the case with chronic stable angina, Oklahoma Heart Institute is unaware of guidelines that use the "risk of CAD" in their algorithms. Risk of short-term death and non-fatal MI is indeed assessed in these patients and when deemed low, a non-invasive risk stratification arm is provided as a possible alternative in current guidelines.

While the use of CCTA in acute coronary syndrome may merit further research, the study referenced in NSTEMI revealed only 15 percent who were shown to be CCTA negative, therefore subjecting the rest to both CCTA and invasive catheterization.

6. **The narrowly defined research parameters CMS proposes will greatly inhibit participation by community cardiologists, who currently perform a majority of CCTA studies for the indications provided in current LCDs. Many groups with well-trained CCTA physicians will not be able to muster the resources to apply and follow their patients in the ways described in the CMS memo.**

   The severe restrictions under which CMS would cover CCTA in clinical research trials would also significantly reduce the amount of long-term, statistically significant data that can be analyzed to demonstrate the effectiveness of CTA. In contrast, a national registry would promote far greater physician participation and result in a more comprehensive set of data that more accurately reflect the current and appropriate uses of CCTA in the diagnosis of cardiac disease.

   There are registries already active in some regions that were carefully derived with appropriateness guidelines embedded and from which data will be forthcoming.

7. **Non-coverage of CCTA for the diagnosis of CAD will result in many Medicare patients having to undergo invasive, higher-risk, more expensive procedures to diagnose CAD,** especially those patients who have symptoms suggestive of coronary disease but have equivocal results on stress echo or stress nuclear perfusion scans. CCTA has allowed many of these patients to avoid invasive cardiac catheterization and the risks inherent in that procedure. Denial of coverage for CCTA places Medicare recipients at greater risk, with higher out-of-pocket costs, and restricts access to state-of-the-art, life-saving technology earlier in the disease process.

8. **Several recent studies, as well as empirical data from Oklahoma Heart Institute, demonstrate that CCTA reduces overall costs to Medicare and third-party insurers while providing excellent diagnostic capabilities and reduced patient risk and discomfort.** Practices nationwide, as well as hospitals, saw cardiac catheterization rates fall in 2006. Although some of the reduction can be linked to the use of statins and other medical advances, there is no question that CCTA is a factor in the decreased number of invasive catheterizations performed. This indicates that CCTA is not only a good clinical choice for many patients in terms of risk and comfort, but also is a fiscally responsible choice for both the Medicare program and its beneficiaries.

In closing, Oklahoma Heart Institute respectfully requests that CMS:

- Allow local Medicare contractors to continue coverage of CCTA for the diagnosis of CAD under their existing LCDs to enable Medicare beneficiaries the benefits of this clinically proven, lower-cost and lower-risk technology.

- Eliminate implementation of its proposed CED. Oklahoma Heart Institute recommends that CMS work with the specialty multidisciplinary societies (SCCT, ACC and ACR) to develop criteria for a CCTA registry to minimize the impact on the delivery of appropriate care to beneficiaries. There are several excellent CCTA registries already in existence that may be used as models for a CMS-approved registry to gather clinical data for longitudinal studies.
- Adopt accreditation guidelines, physician credentialing requirements and clinical appropriateness protocols to promote appropriate utilization of CTA for the diagnosis of CAD. The medical specialty societies are at the forefront in the development of these important quality endeavors, and Oklahoma Heart Institute fully supports their efforts and encourages Medicare to work with them in developing similar guidelines.

Oklahoma Heart Institute appreciates this opportunity to comment on Medicare's Proposed Decision Memo regarding Cardiac CTA. Please contact me at 918 595 0235 or via email at cwilliams@oklahomaheart.com if you have any questions.

Sincerely,

Wayne N. Leimbach, MD
President of Oklahoma Heart Institute

**TO:** Joseph Chin MD

JoAnna Baldwin, MS

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244

**FROM:** Ronald P. Karlsberg, MD, FACC, FAHA, FACP
Clinical Professor of Medicine, David Geffen School of Medicine, UCLA
Cardiovascular Medical Group of Southern California
Director of advanced Imaging
414 North Camden Drive, Suite 1100
Beverly Hills, California 90210
http://www.cvmg.com Karlsberg@cvmg.com
310.278.3400 FAX 310.278.1240 Cell 310 508 7004

**SUBJECT:** NCA for Computed Tomographic Angiography (CAG-00385N)

**Date:** 1/9/2008

---

Thank you for the opportunity to respond to the NCA for Computed Tomographic Angiography (CCTA) (CAG-00385). As Advanced Imaging Director for Cardiovascular Medical Group of Southern California, we are writing this memo to object to the proposed NCA for CCTA and to provide data CMS has perhaps overlooked or was not previously aware of.

Cardiovascular Medical Group of Southern California (CVMG), an urban referral and primary care cardiology practice with 17 cardiologists and a base of 40,000 active patients, recognized that the evaluation of the cardiac patient might undergo a major shift as a result of CCTA technology and in cooperation and collaboration with internationally recognized leaders (Harbor UCLA - Matthew Budoff M.D.; Cedars Sinai Medical Center - Daniel Berman M.D.) installed a 64-slice CT scanner on-site in the office in August of 2005. This installation was not as an independent imaging center but predominately for our own patients. This provided a unique environment to study the effects of this technology as it was made available to patients and integrated into an office practice where outcomes can be more closely monitored. This memo reviews our experience with CCTA integrated into the practice of Cardiology and also our experience implementing the California LCD currently in effect.

1. **The Proposed NCA will create an appeal nightmare for the Medicare Health Care System**: In the year 2006 Medicare carriers in the state of California issued T codes and stopped reimbursement for Cardiac CT which was previously billed using older non specific codes. As a result of these actions, reimbursement for Cardiac CT was terminated for most of the calendar year 2006. CVMG undertook the effort to individually appeal nearly 400 cases to the Medicare court of appeal and presented detailed documentation and live expert testimony for each case to appeal the rejections. The premise for rejection for reimbursement was made by the carriers on two grounds: (1) No California Local Coverage Determination was issued until November 2006. (2) The carrier challenged the medical necessity. The decision by the local Medicare carrier was overturned in each case by independent Superior Court judges and commissioners

from numerous Federal venues. This "case-by-case" review by the medically informed judges, independent of the challenging Medicare carrier, clearly demonstrated that the value of CCTA was understood by the judicial process. Each and every one of the Medicare carrier were overturned by numerous independent Federal judges and commissioners which speaks volumes for the potential disaster that the pending NCA for CCTA will have on our health care system should the numerous provider in each state be again be forced to individually appeal rejections for reimbursement by local Medicare carriers based on the poorly thought out, inadequately vetted, and scientifically invalid proposed NCA.

2. **CVMG has demonstrated positive health care outcomes and substantial reductions in the cost of health care as the result of office integrated CCTA:** In collaboration with Harbor UCLA and Cedars Sinai Medical Center the results of CCTA integrated into a Cardiology office environment has been presented at numerous regional, national and international meetings.

   In summary these documented effects of integrated office based CCTA have been:

   - A nearly 50% reduction in invasive angiography from before office integrated CCTA resulting in a shift of treatment and diagnoses from the very expensive hospital environment to the more efficient less expensive outpatient environment in the setting of reduced coronary percutaneous intervention.

   - Dramatically improved stratification of symptomatic intermediate risk normal patients who do not need further treatment or cardiac testing from those with significant coronary artery disease without the use of invasive angiography.

   - Enhanced treatment and compliance of hyperlipedemic patient with near normal cholesterol (minus 20%) and few risk factors whose anatomic disease that would not be identified with any other technology short of invasive angiography.

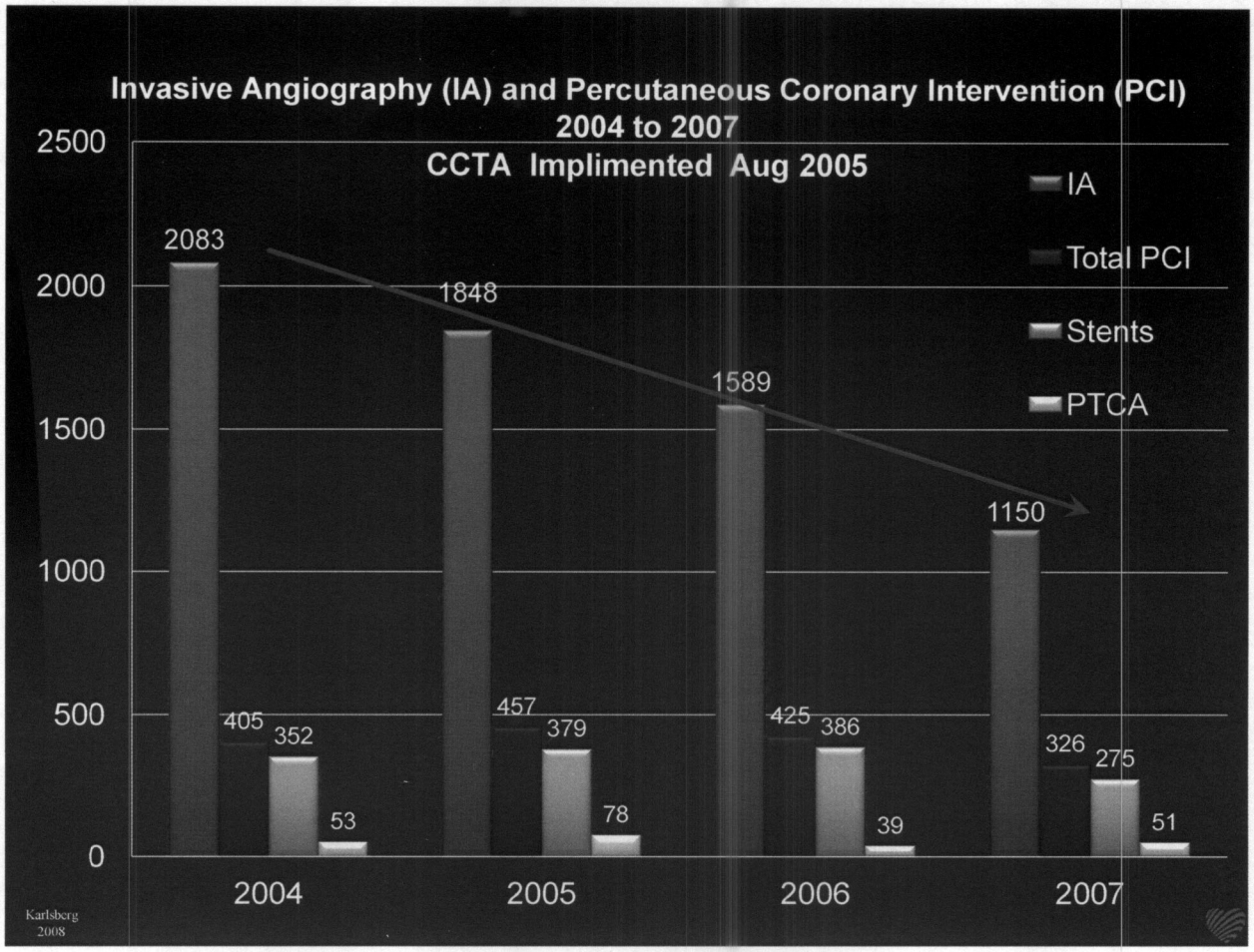
   - Reduced utilization of myocardial perfusion imaging (14%) and treadmill testing (50%) with a potential to reduce utilization of myocardial perfusion imaging by more than 50%.

These results have been presented to peer reviewed national and international meetings in the form of abstracts and presentations and have been submitted in papers pending publication.

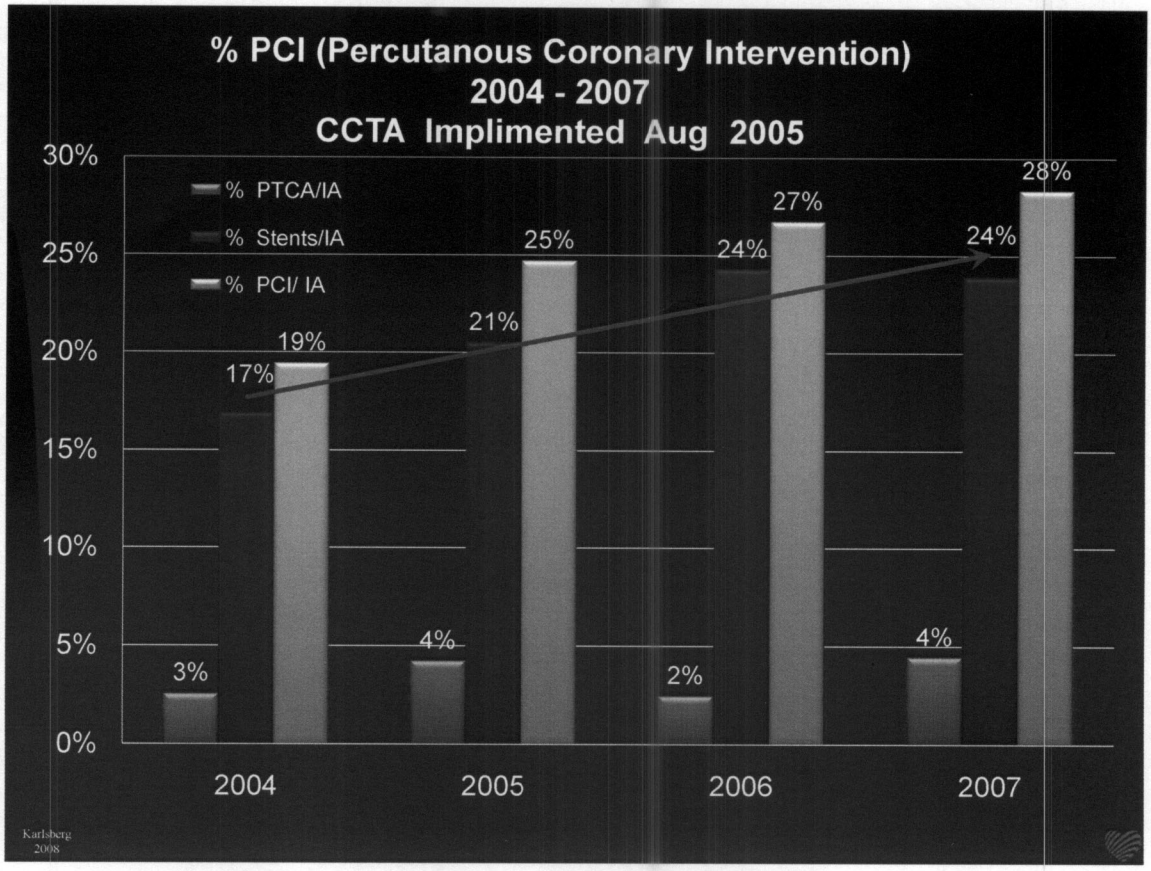
One critical CMS issue we would like to highlight in this memo is the premise that CCTA reduces the need for invasive angiography since this would have a major impact on health care economics, outcomes and morbidity and mortality for the nation. The issue of the effects of CCTA on invasive angiography volume and intervention was cited by CMS as a major endpoint required for the establishment of a national policy for reimbursement of CCTA:

- **CMVG has shown in an office environment that CCTA reduces the need for invasive angiography and aids in getting the right patient to the catheterization lab in the setting of an overall reduced incidence of percutaneous coronary intervention. The results are striking and are presented below.**

- **Patients and the health care system would be harmed if CMS were to ignore and not consider these compelling reductions in invasive angiography related to CCTA integrated into the care of the cardiac patient.**

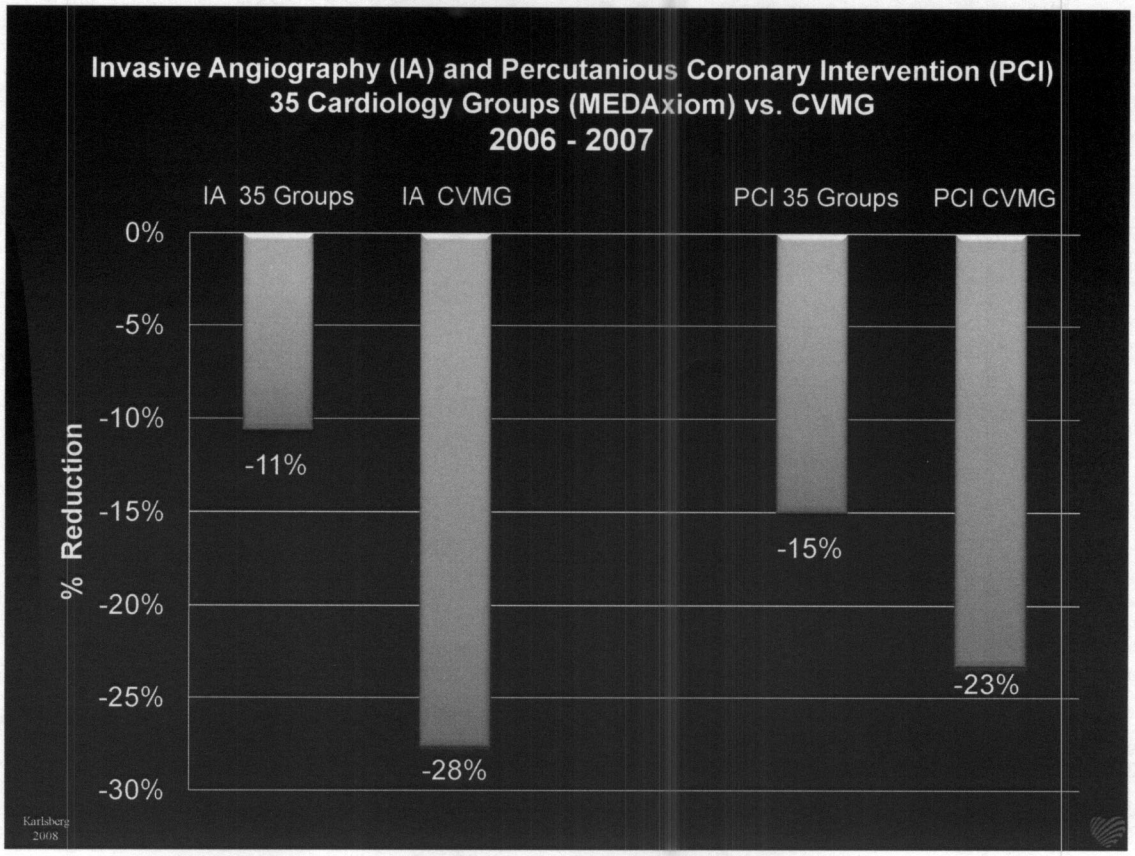



This graph shows the number of invasive angiograms performed by CVMG from 2004 to 2007. By 2007 with wide adoption of CCTA, implementation of the California LCD, and also a better understanding of correlation between CCTA and invasive angiography there was a nearly 50% drop in diagnostic angiography and a reduction in the number of PCIs. The linear trend line is shown in red. A national database (MedAxiom) of 35 large practices showed an 11% drop (see below) in invasive angiography while CVMG with CCTA fully integrated into the practice experienced nearly a 50% drop since 2004. PCIs went from 405 in 2005 to 326 in 2007 or a reduction of 20% indicating that the availably of CCTA not only reduced angiography but this occurred in the setting of reduced PCIs.




This graph shows the % PCIs to diagnostic invasive angiograms over the four years in the setting of the reduced incidence of PCI. The percentage of PCIs to diagnostic invasive angiograms increased from 19% to 28% during the four years suggesting that the proper individuals, those in need of intervention, reached the catheterization lab. CCTA clarified the diagnosis in patients with positive, equivocal and also false negative myocardial perfusion imaging, exercise echo or treadmill testing and unclear clinical presentations. Patient's pre and post cardiac transplant, patients in need of non coronary surgery and with defined coronary anatomy from CCTA (for example, aortic valve, aortic, and mitral valve) went to surgery without invasive angiography. Many symptomatic patients with previous stent placement or bypass did not require repeat invasive angiography. Some patients with totally closed grafts or closed stents were not sent back to the lab for additional intervention attempts when CCTA define the chances of a successful procedure as low. Patients with cardiomyopathy no longer had invasive diagnostic angiography to distinguish ischemic from non ischemic cardiomyopathy. Patients in need of EP studies (for example ablation and placement of biventricular pacers) did not require procedural imaging and had a shorter potentially safer procedure.

Importantly, the availability of CCTA integrated in a practice setting did not lead to increased angiography or PCI rather there were substantially reduced diagnostic angiograms, fewer PCIs and a higher percentage of patients reaching the lab in need of PCI. Of course, many compounding factors influenced these results, but the trend lines are clear. CCTA did not increase angiography, did not increase PCI and CCTA aided the proper individuals reaching the catheterization lab in the setting of an overall lower incidence of interventions.




This graph shows the volume of Invasive Angiography and PCI in 35 Cardiology practices obtained in a national Survey conducted by MEDAxiom. CVMG had a greater reduction in PCI compared to other practices but also a substantially greater reduction (nearly 3-fold) in unnecessary invasive angiography which is associated with significant morbidity, mortality and cost. With increasing spatial and temporal resolution of evolving CCTA technology, we can expect additional reductions in invasive angiography. Nevertheless, the opportunity to the nation is currently present to implement this approach with available cardiac CT resolution. These impressive changes occurred despite stable parameters in other aspects of the practice and also despite the addition of new physicians.

Why was invasive angiography volume reduced? Even before November of 2007 when the California LCD (L22517) was issued, CVMG physicians viewed CCTA as an opportunity to replace invasive angiography in certain circumstances. The California LCD supported this viewpoint and reimbursed for CCTA with the following indications. From the California LCD (L22517):

1. Facilitation of the diagnostic cardiac evaluation of a patient with signs or symptoms strongly suggestive of coronary artery disease (e.g. chest pains, anginal equivalent, angina, newly abnormal electrocardiogram). Depending on the clinical presentation, the MDCT for coronary artery evaluation may precede stress testing, or it may be used to clarify a stress test that is non-diagnostic, equivocal, or is inadequate in explaining the patient's symptoms.

2. Facilitation of the management decision of a symptomatic patient with known coronary artery disease. (e.g., post-stent, post CABG) when the results of the MDCT may guide the decision for repeat invasive evaluation.

3. Assessment of suspected congenital anomalies of coronary circulation or great vessels.

4. Assessment of the patient with suspected aortic dissection or aortic injury.

5. Facilitation of diagnostic evaluation and management of an asymptomatic or symptomatic patient at high cardiovascular risk (e.g. left ventricular systolic dysfunction of unknown etiology, diabetic patients with multiple risk factors for atherosclerosis).

6. Assessment of coronary artery anatomy prior to non-coronary cardiovascular surgery (e.g. valve repair or replacement, ascending aortic aneurysm or dissection repair) or when additional information regarding anatomic location of coronary grafts prior to repeat coronary surgery is needed.

7. Facilitation of anatomic evaluation of patients who are being evaluated for therapeutic electrophysiology procedures in which a detailed knowledge of the heart and great vessels is needed and in some cases, following such procedures,(e.g. suspected pulmonary vein stenosis).

8. To assess coronary anatomy following technically inadequate catheter coronary angiography (e.g. an internal mammary artery, a coronary vein bypass graft or an anomalous native coronary takeoff that could not be engaged.

9. To assess coronary anatomy following heart transplantation at a time in which catheter coronary angiography would otherwise be indicated, CTA anticipated to be used in place of angiography.

3. **In summary:**

CCTA integrated in an office setting has shown important positive outcomes both with regard to the medical and invasive strategy in the management of coronary artery disease.

Clearer stratification of patients in need of invasive therapy, better definition of disease, more aggressive and compliant medical therapy and at a lower cost has already been achieved.

The data supports the use of the California LCD which was implemented during the year of 2007 when our most dramatic results in reduced invasive angiography were accomplished.

**To return to the conundrum of providers appealing hundreds of thousands of cases to federally appointed judges and commissioners in 50 different states is a national disaster that can be avoided.**

**We propose that at this time a National Coverage Determination be deferred and the practice of each state determining the needs of its citizens remains in place**. This approach has been **proven** in the state of California where CCTA has been integrated into an urban cardiology practice and has resulted in positive outcomes and reduced cost to the health care system.

## Select Publications

1. Integrated Coronary CTA in an Office Based Cardiology Practice Reduces Myocardial Perfusion Imaging in the Setting of Increased Identification of CAD and Stable Office Economics – A first Year Experience. Karlsberg RP, Thomson LEJ, Friedman JD, Berman DS, Budoff MJ. Journal of Cardiovascular Computed Tomography. Vol.1, No. 1S, July 2007. S10, 26.

2. Integrated Coronary Computed Tomographic Angiography (64 slice) in an Office Based Cardiology Practice Reduces Myocardial Perfusion Imaging and Exercise Treadmill Testing in the Setting of Increased Identification of CAD, and More Aggressive Lipid Management. Ronald P. Karlsberg MD, FACC, Louise E.J. Thomson MB, ChB, Matthew J. Budoff, MD, FACC, John D. Friedman, MD, FACC, Daniel S. Berman, MD, FACC, submitted, in press.

3. Personal communication: MedAxiom Patrick J. White President MedAxiom Direct: 248-374-1956 Mobile: 248-756-4659 Email: pwhite@medaxiom.com

4. California LCD for CCTA:
http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=22517&lcd_version=7&show=all

## Research Grants

1. A Phase 3, Open-label, Multi-Center Study to Determine Efficacy and Safety of VISIPAQUE™ (iodixanol) Injection for Use in Intravenous Contrast-Enhanced CT Angiography of Coronary Arteries DXV 301, 2006.

2. A multi-centre, randomized, double-blind, parallel group, phase IV study to compare the renal effects of the non-ionic iso-osmolar contrast medium, iodixanol 320 mg I/mL (VisipaqueTM), with the non-ionic low osmolar contrast medium, iopamidol 300 mg I/mL, in subjects with impaired renal function and diabetes mellitus undergoing multi-detector-row helical CT. Protocol DXV406, 2006.

3. PICTURE: Perfusion Imaging and CT –Understanding Relative Efficacy; Contrast-Enhanced Cardiac Computed Tomography (CT) Using GE LightSpeed Volumetric Computed Tomography (VCT) Scanner for the Detection of Coronary Artery Disease: A Prospective Multi-Center Study Comparison with Cardiac Radionuclide Imaging. 2007.

January 10, 2008

John M. Gilbert, III, MD
Rocky Mountain Radiologists, P.C.
1873 South Bellaire Street, #420
Denver, CO 80222

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Joseph Chin, M.D. and JoAnna Baldwin, M.S.
P.O. Box 8014
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N

I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to deny or reduce coverage for Cardiac Computed Tomography Angiography (CCTA).

After reviewing the proposed changes, I respectfully ask that CMS consider:

1) CCTA has substantial clinical utility in ruling out coronary disease in both acute care and non-acute care settings.

(2) The proposed NCD does not fully reflect the current state of evidence in support of CCTA in regard to symptomatic patients with chronic stable angina at intermediate risk of CAD.

(3) Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive diagnostic tests.

(4) It is entirely inappropriate for CMS to demand evidence that proves that "coronary CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other setting." Health outcomes depend on numerous factors, including, for example, the efficacy of treatment, patient compliance with medication protocols, the severity of disease, and other factors. For this reason, it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered.

(5) In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach.

(6) Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

I respectfully request that CMS delay implementing the Proposed National Coverage Determination (NCD) Memo for Cardiac Computed Tomography Angiography (CCTA), CAG-00385N, and reconsider allowing local carrier determinations of coverage until the above are considered and incorporated into coverage determination recommendations.

Thank you for your consideration.

Sincerely,

John M. Gilbert, III, MD

Thomas Jefferson University | Jefferson Medical College

January 12, 2008

Steve Phurrough, M.D., MPA
Director, Coverage and Analysis Group
CMS
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Phurrough,

As director of cardiac CT at Thomas Jefferson University Hospital in Philadelphia, I was surprised by the determination of CMS that there is not sufficient evidence to support reimbursement for cardiac CTA. I agree that there are many situations for which cardiac CTA is not an appropriate diagnostic test, but there are many situations for which cardiac CTA is the optimal choice. I wish to emphasize those clinical applications for which we have found tremendous utility in coronary CTA.

Over the past 4 years I have personally performed and interpreted approximately 3,000 cardiac CT cases in a university hospital setting. I present an outline below of several clinical scenarios for which I believe that there is clear evidence that cardiac CT is the most cost-effective and least invasive approach to the relevant clinical issues. Much of what follows is directly excerpted from a textbook that I have recently published (Clinical Cardiac CT – published by Thieme 2008). I would be happy to testify about these issues in person if you are willing to hold a hearing on the matter.

1. **Suspected coronary anomalies:** Coronary anomalies are an important cause of sudden death in young athletes. Coronary CT angiography provides a non-invasive assessment of coronary anatomy, and a clear demonstration of coronary anatomic variations and anomalies. Because CT demonstrates adjacent anatomical structures as well as coronary arteries, MDCT provides a unique opportunity to assess the origin and course of a coronary artery relative to the aortic root, pulmonary artery and myocardium. CT angiography is often superior to conventional catheter arteriography for the diagnosis of cornary anomalies. [1] In my practice, coronary CTA is often requested after a conventional cardiac catheterization when there is residual uncertainty about the course of the anomalous coronary artery. Coronary CTA should be the first line examination in these patients.

2. **Evaluation of chest pain in a patient with low pre-test probability of disease**: In this setting, coronary CTA is an excellent alternative to the nuclear perfusion stress test. "A normal CT coronary angiogram allows the clinician to rule out the presence of hemodynamically relevant coronary artery stenoses with a high degree of reliability".[2] In patients who do not have a high pretest likelihood of coronary stenosis a normal CT coronary angiogram serves to obviate any further need for a diagnostic coronary work-up.[3] In my hospital practice, cardiac CTA is often performed as an additional test after a positive nuclear stress test when the referring physician suspects a false positive result. As you know, the radiation dose of coronary CT angiography without prospective dose modulation is similar to that of nuclear scintigraphy, while the negative predictive value of CT is superior to that of nuclear scintigraphy. Furthermore, in a patient with a stable, regular cardiac rhythm, prospective dose modulation and/or "step and shoot" techniques reduce the radiation dose with cardiac CTA to approximately half the dose of nuclear scintigraphy. It is therefore reasonable for CT angiography to provide a first line alternative to nuclear scintigraphy for evaluation of chest pain in a patient with low/intermediate risk for coronary artery disease.
3. **Chest pain in the emergency room**: For an emergency room patient presenting with chest pain, CT can provide a "triple rule-out" evaluation of the pulmonary arteries for pulmonary embolism, the thoracic aorta for dissection and the coronary arteries for significant stenosis. There is ample evidence in the CTA literature that a normal coronary CTA excludes the presence of significant coronary disease.[2, 3] With a single examination requiring no more than 100cc of intravenous contrast, CT angiography can evaluate all three of these serious vascular causes of chest pain, as well as non-vascular extracardiac causes of pain. A recent review of emergency room patients at Jefferson Hospital demonstrates that a triple rule-out CTA can provide coronary image quality that is equal to that provided by a dedicated coronary CTA (manuscript in preparation). The pulmonary artery evaluation with a gated CTA is actually superior to that provided by our standard CTA for pulmonary embolism. In another study of the last 200 emergency room patients at Thomas Jefferson University Hospital, the

triple rule-out coronary CTA examination provided an alternative diagnosis that explained the presenting symptoms in 11% (ie. Aortic dissection, pulmonary embolism, pneumonia etc), demonstrated the presence of significant coronary disease requiring conventional catheterization and interventional treatment in 11%, and allowed the prompt discharge of approximately 70% of patients after the CTA study (manuscript is currently under review for publication in Radiology). Evaluation of the emergency room patient with chest pain who is considered low risk for coronary disease is a cost-effective application – it speeds up the diagnostic process and avoids multiple diagnostic tests such as CT for pulmonary embolism along with a nuclear stress test. In the setting of acute chest pain, the CTA also avoids the need for stressing a patient who could potentially have acute coronary syndrome.

4. **Bypass patients**: CT angiography is useful in both the pre-operative planning of coronary bypass surgery, and in the post-operative evaluation of bypass grafts,[4] and especially in the setting of repeat cardiac surgery after previous bypass.[5] CT angiography clearly demonstrates the location of bypass grafts relative to other cardiac and thoracic anatomic landmarks. The location of grafts can be very useful for repeat surgery. Venous bypass grafts are easily evaluated for stenosis or thrombosis. Arterial bypass grafts are more difficult to evaluate because of their smaller size, but the sensitivity/specificity of CTA for bypass graft occlusion with a 64 detector system is well over 90%. Native vessels are difficult to evaluate in these patients due to extensive calcification. Future improvements in CT technology are likely to expand this application as well.
5. **Pre-operative planning for ablation in the left atrium**: CT evaluation of pulmonary vein anatomy prior to ablation for atrial fibrillation provides a roadmap for ablation around the pulmonary veins. CT data can be merged with fluoroscopic data in the EP lab to facilitate what is a very delicate procedure, to insure that the ablation is performed in the optimal locations and to avoid the complication of pulmonary vein stenosis that can occur when ablation is performed at the ostium of a small pulmonary vein.

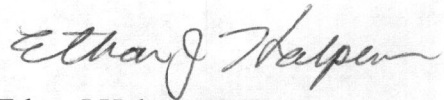
6. **Pre-operative cardiac clearance in low risk patients:** There are many patients for whom nuclear scintigraphy and /or cardiac catheterization are recommended prior to surgery. In my practice, coronary CTA is often used in this population to follow an abnormal stress test. Patients with abnormal stress results are cleared for surgery on the basis of a normal coronary CTA. Given the high negative predictive value of coronary CTA, coronary CTA would be an appropriate first-line evaluation for pre-operative cardiac clearance in low risk patients. In this scenario, coronary CTA could obviate the performance of negative cardiac catheterization studies.
7. **Pre-operative planning for placement of a biventriculoar pacemaker**: CT evaluation can be used for coronary vein mapping prior to placement of a biventricular pacemaker. The size and location of coronary veins can be used to guide the procedure.
8. **Assessment of suspected myocardial perforation**: Coronary CTA is useful to assess the extent of a rent in the myocardium when a small psuedoanuerysm is suspected on a left ventriculogram in the cath lab. The left ventriculogram can demonstrate the presence of a tear in the myocardium, but the extent of myocardial penetration is much more clearly assessed on CT because the myocardium itself is clearly visualized. The determination of extent of myocardial penetration can be used to triage patients to watchful waiting versus emergency cardiac surgery.
9. **Pre-operative assessment for aortic valve replacement**: Coronary CTA can be used to evaluate the coronary arteries along with the aortic root and aortic valve prior to aortic valve replacement. A CT evaluation is often ordered on these patients to evaluate for calcification of the ascending aorta even after a catheterization is performed. In this situation, a single coronary CTA can replace a cardiac catheterization and an echocardiogram. The excellent negative predictive value of coronary CTA for coronary disease allows the exclusion of significant coronary disease prior to surgery. The three-dimensional data acquired at CT allows precise measurements of the aortic root for planning of a valve replacement.

To balance this discussion, there are clearly several applications that are not appropriate for coronary CTA at this time. Screening of asymptomatic patients is not appropriate since there is no evidence that intervention will improve morbidity/mortality in this group. Intermediate to high risk patients with suspected coronary disease may not be appropriate candidates for coronary CTA since the examination is unlikely to yield a normal result, and there is insufficient outcomes data on the meaning of mild/moderate coronary stenosis in this patient group. High risk patients with chest pain should be sent directly to the cath lab for conventional cardiac catheterization. Assessment of coronary stents is limited by artifact from the metallic stents. Assessment of stents is particularly problematic for stent sizes below 3.5mm. Assessment of native vessels in patients with known coronary disease is often limited by coronary calcification. Assessment of myocardial perfusion is experimental and quite variable among different institutions.

Given the published literature demonstrating the high negative predictive value of coronary CTA, this technique is clearly useful in many low risk patients in whom it will obviate a conventional cardiac catheterization. Although there is not much published outcomes data with coronary CTA, there are many studies comparing coronary CTA to cardiac catheterization. Even without the outcomes data I believe that the data on sensitivity/specificity of CTA versus cardiac catheterization justifies the application of coronary CTA in the clinical scenarios mentioned above.

I hope that you find my comments useful. I would be happy to answer any questions that you have. Thank you for you attention to my response.

Sincerely,



Ethan J Halpern, MD
Director, Cardiac CT
Professor of Radiology
Thomas Jefferson University

References:


1. Kim SY, Seo JB, Do KH, Heo JN, Lee JS, Song JW, Choe YH, Kim TH, Yong HS, Choi SI, Song KS, Lim TH. Coronary artery anomalies: classification and ECG-gated multi-detector row CT findings with angiographic correlation. *Radiographics* 2006; 26:317-33.
2. Budoff MJ, Achenbach S, Blumenthal RS, Carr JJ, Goldin JG, Greenland P, Guerci AD, Lima JA, Rader DJ, Rubin GD, Shaw LJ, Wiegers 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(16):1761-91.
3. Achenbach, Stephan. Computed tomography coronary angiography. Journal of the American College of Cardiology. 2006, 48:1919-1928.
4. Herzog C, Wimmer-Greinecker G, Schwarz W, Dogan S, Moritz A, Fichtlscherer S, Vogl TJ. Progress in CT imaging for the cardiac surgeon. *Semin Thorac Cardiovasc Surg* 2004; 16:242-248.
5. 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.

## Baldwin, JoAnna F. (CMS/OCSQ)

**From:** CMS CAGInquiries
**Sent:** Monday, January 14, 2008 11:46 AM
**To:** Baldwin, JoAnna F. (CMS/OCSQ)
**Subject:** FW: Computed Tomographic Angiography (CAG-00385N).

---

**From:** Michael Lipsitt [mailto:lipsitt@bellsouth.net]
**Sent:** Saturday, January 12, 2008 9:07 AM
**To:** CMS CAGInquiries
**Subject:** Computed Tomographic Angiography (CAG-00385N).

Re Medicare NCD

Dear Sirs:

I am a practicing cardiologist in Atlanta GA. Our group has had a 64 slice CT for the past year. It is our experience that this procedure has considerable clinical utility in ruling out coronary disease in a non-acute care setting. We have been able to reduce the number of catheterizations especially in those patients with intermediate probability of disease and an equivocal DIMPS. Denying coverage for CCTA for the diagnosis of CAD will limit Medicare patients' access to this valuable technology, resulting in the performance of more costly and invasive in hospital diagnostic tests. I feel that it is entirely inappropriate to demand that a diagnostic technology, such as CCTA, demonstrate an impact on health outcomes in order to be covered. We have many examples of non cardiac diagnoses that we made because of findings on CCTA ordered for chest pain. In light of the difficulties involved in structuring randomized clinical trials to address the specific clinical issues identified in the proposed NCD, CMS should consider a registry approach instead of, or in addition to, the clinical trial approach. Rather than cutting off coverage precipitously, CMS should consider allowing local carrier decisions to remain in place, at least pending enrollment of the first clinical trial or establishment of an approved registry.

Many thanks for your consideration,

Michael Lipsitt MD FACC SCAI

Cardiovascular Group PC

755 Walther Road

Lawrenceville, GA 30045

University of Michigan
Health System

**Hospital Financial Services**

University of Michigan Health System
2500 Green Road, Suite 100
Ann Arbor, Michigan 48105
Phone: (734) 936-7812

January 11, 2008

Steve E. Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mailstop C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Proposed National Coverage Decision (NCD) limiting coverage for cardiac CT

Dear. Dr. Phurrough:

I am writing on behalf of the University of Michigan Health System (UMHS) in response to CMS' proposed National Coverage Decision for Computed Tomographic Angiography (CAG-00385N). UMHS is a major academic medical center located in Southeast Michigan. Our Health System includes a highly ranked hospital and medical school and, among its many excellent specialty care programs, one of the premier cardiovascular centers in the country.

UMHS is very disappointed in the CMS proposed restrictions on the use Computed Tomographic Angiography (CCTA), and strongly urges the Agency to rescind or alter its proposed NCD. The proposal would significantly limit access to a clinically appropriate technology for Medicare beneficiaries and is contrary to the local coverage determinations that have made CCTA available in all fifty states and the District of Columbia. This proposed restriction of a widely accepted, clinically appropriate and rapidly maturing technology is unprecedented, and unwarranted.

UMHS has been performing cardiac CT examinations for a decade, including CCTA specifically since early 2005 on 64 detector CT scanners. We have found it to be a very useful, non-invasive method of coronary interrogation. One of the benefits of coronary CT is to avoid cardiac catheterization, a much more costly and invasive test. For patients with suspected coronary artery disease (CAD), cardiac catheterization is often the only other test that can provide evidence about the presence or absence of significant CAD. The very high negative predictive value of coronary CT allows patients to avoid the cost, expense and potential complications of cardiac catheterization. For coronary artery anomalies, cardiac CT is the test of choice of our cardiothoracic radiologists.

In reading the NCD document, it appears that CMS was selective in drawing conclusions about the evidence presented. The majority of the clinical studies cited in the document provided from partial to full support for the use of CCTA; and most of public comments were in favor of continuing to allow local contractors to dictate coverage. Furthermore, it is our understanding that the majority of studies based on the use of 64-slice equipment were not even considered in the CMS evaluation.

University of Michigan
Health System

**Hospital Financial Services**

University of Michigan Health System
2500 Green Road, Suite 100
Ann Arbor, Michigan 48105
Phone: (734) 936-7812



UMHS is fully committed to providing appropriate evidence-based care, and we support more study of the effectiveness of CCTA for various defined conditions. In fact, UMHS has a leadership role in a Michigan-wide collaborative study sponsored by Blue Cross Blue Shield of Michigan. the BCBSM Advanced Cardiovascular Imaging Consortium of Michigan. This regional consortium is intended to improve the quality of care for patients undergoing CCTA as a collaborative quality initiative, encouraging the appropriate and judicious use of this and other emerging cardiac imaging technologies, including the evaluation of practice patterns associated with the use of CCTA and related clinical outcomes. As part of this effort, the consortium has created a cardiac CT registry for the purpose of collecting data from each of the participating hospitals to define the role of this technology among of the among the number of cardiac tests that are available, along with establishing appropriateness and quality criteria.

If CMS believes that additional guidelines and/or appropriateness criteria are needed with respect to CCTA, perhaps it should consider an approach similar to what we have in place in Michigan, in lieu of virtual elimination of coverage that CMS has proposed.

Again, we strongly urge CMS to allow the local coverage decisions to remain in force and not to implement the proposed NCD. Thank you for your consideration of these comments.

Thomas Marks
Senior Director and Revenue Cycle Officer
University of Michigan Hospitals and Health Centers

**Beaumont**®
William Beaumont Hospital
Royal Oak

January 10, 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

Dear Mr. Steve E. Phurrough, MD, MPA:

I am writing this letter in response to the Centers for Medicare and Medicaid Services (CMS) posting of a proposed National Coverage Decision (NCD) limiting coverage on CTA of the coronary arteries.

I 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 access for clinically appropriate indications with this technology. The proposed national coverage determination is contrary to current local coverage determinations (LCDs) in place in all fifty states and the District of Columbia.

The local coverage determination (LCD) process has evaluated coronary CTA in all 50 states and the District of Columbia, and has provided availability of coronary CTA reimbursement for CMS beneficiaries for well-defined indications.

Approximately one half of the available evidence with 64 slice CT scanners has not been considered in the draft proposal. The proposed NCD does not fully consider all of the available evidence. As the standard of practice in 2007 is to perform coronary CTA with MDCT scanners of 64-slices, we encourage CMS to consider the large numbers of 64-slice coronary CTA studies omitted from the proposed NCD in lieu of other studies involving outmoded 4-, 8- and 16-slice MDCT scanners. 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.

The proposed NCD will limit access to a very useful, non-invasive method of coronary interrogation in favor of more costly and more invasive, reimbursed methods (e.g., invasive catheterization).

In summary, I Urge CMS to allow the LCDs to remain in force in lieu of implementing a NCD that requires coverage with evidence development.

Sincerely,

Kostaki G. Bis, MD, FACR

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769
248.898.5000

1/9/08

Dear Dr. Phurrough,

As a diagnostic radiologist, former CMS CAC member and executive member of the DC chapter of the District of Columbia Metropolitan Radiological Society (DCMRS) I am writing this letter to express my concern regarding the recent CMS LCD which would limit coverage of CTA of the coronary arteries. We disagree with the CMS conclusions in this proposed coverage determination and believe that if implemented, the policy would have a negative impact on Medicare beneficiaries by limiting access for clinically appropriate indications with this technology. The proposed national coverage determination is contrary to current local coverage determinations (LCDs) in place in all fifty states and the District of Columbia. The local coverage determination (LCD) process has evaluated CCTA in all 50 states and the District of Columbia, and has provided availability of CCTA reimbursement for CMS beneficiaries for well-defined indications. Approximately one half of the available evidence with 64 slice CT scanners has not been considered in the draft proposal.

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, we 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. 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. The proposed NCD will limit access to a very useful, non-invasive method of coronary interrogation in favor of more costly and more invasive, reimbursed methods (e.g., invasive catheterization). We urge CMS to allow the LCDs to remain in force in lieu of implementing a NCD that requires coverage with evidence development (CED).

Sincerely,

Alex Kladakis, MD
Washington Radiology Associates, PC
Alternate Councilor DCMRS

Beth Israel Deaconess Medical Center

A teaching hospital of Harvard Medical School

**Melvin E. Clouse, MD, FAHA, FACR, FSIR**
*Emeritus Chairman of Radiology and*
*Director, Radiology Research*

*Deaconess Professor of Radiology*
*Harvard Medical School*

January 8, 2008

Steve E. Phurrough, MD, MPA
Director, Hypergen Analysis Group CMSRECTA
Mail Stop - C1-09-067500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Phurrough:

Based on the evidence used to make the decision of CMS, I can only concur. However, I noticed that you do not have the data from the **Core64**, an international multi-center study performed at 9 leading institutions around the world and the **ACCURACY** study performed at 16 leading centers in the United States. These studies were done in a prospective completely blinded fashion and were registered on the ClinicalTrials.govwebsite. In Core64, the MDCT and invasive coronary artery studies were sent to separate reading centers for analysis prior to collation to evaluate the accuracy of MDCT. This study was designed to compare MDCT with coronary angiography to detect >50% stenosis compared to quantitative coronary arteriography on a per patient basis, per vessel and prediction of revascularization compared to catheter QCA. The nine participating centers included the Beth Israel Deaconess at Harvard; Johns Hopkins Hospital, Johns Hopkins and Bayview Medical Center, Baltimore, MD; Toronto General Hospital, Canada; Mount Elizabeth, Singapore; Leiden University, Netherlands; Humboldt University Charite, Berlin; and the University of San Paolo, Brazil. The sensitivity, specificity, positive predictive value, and negative predictive value were 85%, 95% 90%, 91%, and 83% respectively (on a per-patient basis). In comparing Catheter QCA with MDCT for revascularization, the area under the ROC curve was 0.84 (0.79-0.88) for MDCT and 0.82 (0.77-0.86) for Catheter QCA, p=0.36. This study involved 291 patients assessing all vessels >1.5 mm with a calcium score < 600 Agatston in all patients. Eighty-nine patients with scores above 600 Agatston units are segregated for follow up outcome. The study was closed January 31, 2007 and follow up of all patients enrolled will be evaluated after January 31, 2008 for outcome. It was also done on a per-vessel analysis, again with assessment of all segments.

The ACCURACY study reported similar results involving 232 patients. The per-patient analysis shows a sensitivity of 93%, specificity 82%, positive predictive value (PPV) 97% and negative predictive value 84%. These data were presented in the "Late Breaking Trials" section at the Radiological Society of North America Annual Meeting on Monday, November 26, 2007.

I realize that single-center studies always report higher sensitivity, specificity, positive and negative predictive value than a multi-center study; however, I believe these studies indicate that on a per-patient patient basis as compared to QCA evaluation of catheter coronary angiography, that our Core 64 study demonstrated that MDCTA was as sensitive as catheter coronary arteriography in predicting revascularization. The area under the curve in our 291 patients with a prevalence rate of 34% demonstrated 0.80 for MDCTA (079-0.88) compared to catheter QCA, 0.82 (0.77-0.86) with p=0.36. The disease prevalence in the Core64 study evaluating for 50% stenosis was 56%. In the ACCURACY study the disease prevalence for >50% stenosis was 12% and 21% for >70% stenosis.

I am enclosing the data from both trials which evaluated a total of 523 patients and reported similar very good results. I hope CMS will reconsider the criteria for reimbursement since these two blinded studies show that patients with a low to intermediate risk of coronary stenosis are likely to benefit from this non-invasive scan and indeed in many instances can replace cardiac catheterization. I agree that it is inappropriate to consider MDCTA as a coronary artery screening procedure, but it will expedite the work up of low to intermediate risk CAD patients presenting with chest pain of undetermined cause in the emergency rooms. MDCTA is much less expensive than myocardial perfusion studies and has demonstrated significant improvement in sensitivity and specificity.

Sincerely,

Melvin E. Clouse, MD
Deaconess Professor of Radiology
Harvard Medical School

Thomas Jefferson University | Jefferson Medical College

Vijay M. Rao, MD
Professor and Chair
Department of Radiology

Founded 1824

Jefferson Medical College

Jefferson College of Graduate Studies

Jefferson College of Health Professions

Jefferson University Physicians

January 11, 2008

Steve Phurrough, MD, MPA
Director
Coverage and Analysis Group, CMS
Re: CTA
Mailstop C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. Phurrough:

As current and former chairs of the Department of Radiology at Thomas Jefferson University Hospital, we are writing to protest the unnecessarily restrictive recent CMS NCD for cardiac CT angiography (CCTA). The document announcing the NCD, dated December 13, 2007, is flawed, in that it fails to take into account a number of recent publications in the 2007 medical literature documenting the efficacy of 64-detector row CCTA in diagnosing coronary artery disease (CAD) quickly, inexpensively, and noninvasively. The CMS NCD would cover this procedure only for symptomatic patients with chronic stable angina at intermediate risk of CAD; or symptomatic patients with unstable angina at low risk of short term death and intermediate risk of CAD.

These criteria leave out several large categories of patients who would greatly benefit from CCTA. One category includes those patients who present with atypical chest pain, as opposed to stable or unstable angina. In the average cardiac cath lab, about 25% of patients undergoing invasive coronary angiography (ICA) end up having normal studies. These are usually patients who their cardiologist thinks do not have CAD and who have normal or equivocal cardiac stress nuclear scans. But the cardiologist can never be sure the patient doesn't have CAD, so he sends him/her for ICA just to be absolutely sure. These patients can now instead undergo CCTA, which has a negative predictive value close to 100%. They can be saved an unnecessary invasive procedure and Medicare can be saved the high cost of a cardiac cath.

A second category includes those who present to emergency departments with acute chest pain that may not have the attributes of unstable angina. Here again, these individuals often end up going to cardiac cath, or even worse, being discharged with unrecognized CAD that is not detected during the ED workup. CCTA has been shown to be highly useful in this population.

A third category are those with suspected congenital anomalies of the coronary arteries, a potentially lethal condition. These anomalies can be quickly ruled in or out by CCTA. A fourth category are those who have had previous coronary stents or bypass surgery but who now have recurrent symptoms. These patients can now be

www.Jefferson.edu 132 South 10th Street, Suite 1087F, Philadelphia, PA 19107-5244 • 215-955-7264 • Fax: 215-955-6751 • vijay.rao@jefferson.edu

worked up noninvasively with CCTA to determine whether their symptoms are due to new CAD or problems with their bypasses or stents. There are other categories as well. The NCD you recently issued is going to deprive thousands of Medicare beneficiaries of a valuable and needed test.

Here in Pennsylvania, your carrier, Highmark Medicare, has instituted a much more appropriate LCD. Their indications include: (1) emergency evaluation of acute chest pain; (2) cardiac evaluation of a patient with chest pain syndrome (eg anginal equivalent or angina), as an alternative to cardiac cath; (3) management of a symptomatic patient with known CAD (eg post-stent or post-CABG); (4) assessment of coronary or pulmonary venous anatomy; (5) assessment of suspected congenital anomalies of the coronary circulation; (6) diagnostic evaluation of a patient with current uninterpretable or equivocal stress imaging test results; (7) in lieu of routine invasive coronary angiography prior to noncoronary cardiac or aortic surgery in patients at low risk of concomitant coronary disease. These are much more reasonable and clinically appropriate criteria than the severely restrictive ones in the recent CMS NCD. We strongly urge you to either adopt these, or else retract the NCD and let the carriers continue with the LCDs they have already instituted.

Thank you for considering our comments.

Sincerely,

Vijay M. Rao, M.D.
Professor and Chair
Department of Radiology

David C. Levin, M.D.
Professor and Chair Emeritus
Department of Radiology