July 13, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00385N

Dear Sir/Madam:

The Centers for Medicare and Medicaid Services (CMS) has requested input from stakeholders as the Agency formulates a national coverage analysis (NCA) for computed tomographic angiography (CTA). This NCA pertains to the use of CTA for two particular purposes: as a substitute for invasive coronary angiography; and in the evaluation of chest pain in the emergency department. It is our understanding that the NCA, in turn, will be used to determine whether or not a national coverage determination (NCD) regarding these indications is warranted.

We very much appreciate the opportunity to submit comments on this important topic on behalf of the American Heart Association (AHA) and the American Stroke Association (ASA). Our organization has over 22.5 million volunteers and supporters, including members of the general public, health care researchers and clinicians. Each of us is a health care consumer, too. Founded in 1924, we are the nation’s oldest and largest voluntary health organization devoted to reducing death and disability from cardiovascular disease and stroke – the nation’s number one and number three causes of death. We are unique in that our focus is on the consumer-provider nexus where most health care actually occurs. We fulfill our singular mission through research, public and professional education, community-based programs and broad-based advocacy. A very important part of our effort is the development of evidence-based clinical practice guidelines and scientific statements, which are designed to raise awareness of and advise physicians and other providers regarding the prevention, treatment and management of cardiovascular disease and stroke. The Guidelines and Scientific Statements process predicates recommendations on the best scientific data available analyzed by content experts; it is subject to stringent peer review and scrupulous management of conflict of interest.
Current Position

The burden of coronary artery disease (CAD) is immense. It caused 20% of the deaths in the United States in 2004, affecting both men and women in large numbers. The estimated prevalence of CAD is 15,800,000 and the estimated cost is $151.6 billion. Over one million patients each year undergo examination for acute chest pain at an emergency center, at a cost of over $10 billion. Accurate diagnosis is essential to effective treatment of CAD and, increasingly, to its prevention; the latter consideration, though very important, is, at the request of CMS, beyond the scope of these comments. Our Scientific Statement – Assessment of Coronary Artery Disease by Cardiac Computed Tomography – best explicates our current position on this topic (Budoff MJ et al. Circulation 2006;114;1761-1791). These are the pertinent recommendations:

1. CTA is reasonable for the assessment of obstructive disease in symptomatic patients (Class IIa, Level of Evidence: B).
2. CTA in asymptomatic persons as a screening test for atherosclerosis (non-calcified plaque) is not recommended (Class III, Level of Evidence: C).
3. CTA to follow up stent placement is not recommended (Class III, Level of Evidence: C).
4. CTA is reasonable to assess patency of the coronary bypass graft; it is less well-suited for assessment of stenoses within the graft, at the anastomotic site or within the native coronary artery itself (Class IIb, Level of Evidence: C).
5. CTA is a first-choice imaging modality in evaluating known and suspected coronary artery abnormalities (Class IIa, Level of Evidence: C).

In addition, two systematic reviews of the evidence – one performed by the Agency for Healthcare Research and Quality (AHRQ)-supported Evidence-based Practice Center at Duke University (2006) and the other by the Blue Cross Blue Shield Association (BCBSA) Technology Practice Center – identified evidence gaps that may require randomized, controlled clinical trials to fill, particularly regarding the impact of CTA on health outcomes in patients at low and intermediate risk for obstructive CAD.

Though not addressed in the AHA Scientific Statement referenced above, computed tomography, including CTA, is of demonstrated value in excluding causes of chest pain other than acute coronary syndromes, including pulmonary embolism, pneumonia, pleural or pericardial disease, trauma and dissection of the thoracic aorta. Central to the evaluation of chest pain, however, is the understanding that clinical symptoms, characteristic electrocardiographic abnormalities and elevation of biomarkers constitute the only accepted definition for the diagnosis of acute myocardial infarction, for both clinical and research purposes. It cannot be over emphasized that this standard diagnostic schema should be followed promptly in patients suspected of having an acute coronary syndrome, as recommended in previous ACC/AHA guidelines for both ST elevation myocardial infarction and for unstable angina-non-ST elevation myocardial infarction. Other diagnostic imaging studies, e.g. CTA, should not delay this evaluation.

Developing Science

As noted in the AHA Scientific Statement referenced above, cardiac computed tomography, including CTA, has “undergone an accelerated progression in imaging capabilities over the past decade and this is expected to continue for the foreseeable future. As a result (of this rapid
development), the diagnostic capabilities (of the technique), at times, have preceded the critical evaluation of (its) clinical application”. Some of the newer work reflecting this activity, particularly as it applies to the evaluation of chest pain in the emergency room, is summarized in the upcoming ACC/AHA 2007 Guidelines for the Management of Patients with Unstable Angina/Non-ST-Elevated Myocardial Infarction: A Report of the ACC/AHA Task Force on Practice Guidelines, which is scheduled to be released in mid-August. These guidelines will include a discussion of the proper role of CTA in the evaluation of acute chest pain that does not appear in our 2006 scientific statement.

Multiple recent studies, published in 2006 and 2007, document that better instrumentation – multi-detector computed cardiac tomography (64-slice) shows particular promise – coupled with modified scanning protocols, have resulted in improved diagnostic accuracy, with a generally high negative predictive accuracy. Very few, however, are randomized, controlled clinical trials, i.e. the highest level of evidence. More importantly, to be of maximum benefit, new studies must be considered together with older work subject to the Guidelines process referenced above. The knowledge base must be rigorously evaluated as a whole, a process which, unfortunately, requires considerably more time than this request of comments allows.

The reference by Goldstein JA et al. (J Am Coll Cardiol 2007; 49; 863-879) represents one of the few randomized, controlled clinical trials addressing strategies for the further evaluation of chest pain once acute myocardial infarction has been expeditiously considered in the standard fashion. CTA was equivalent to that ‘standard of care’ – diagnostic algorithm, including ECG and cardiac enzymes, with follow-up radionuclide imaging – in identifying or excluding high-grade (>70% stenosis) CAD as the cause of chest pain, reducing both time to diagnosis from 15.0 to 3.4 hours and costs from $1,872 to $1,586. Follow-up over six months failed to identify any major adverse cardiac events in either group. Of note, however, is that 25% of patients had either an intermediate degree of stenosis (26-70%) or a non-diagnostic CTA.

Exposure to ionizing radiation, with its potential for adverse consequences, remains a concern, one study documenting a dose of 14.7mSv (SD = 2.2) for CTA vs. 5.6 (SD = 3.6) for invasive coronary angiography. Cumulative dose needs to be considered for patients who undergo repeat diagnostic evaluations. Optimal imaging is facilitated by lower heart rates (often requiring the administration of beta blockers) and by the injection of a sufficient amount of contrast material. The risk of contrast toxicity for CTA is governed by the same considerations that apply to interventional coronary angiography and, thus, should be both dose-related and vary with co-morbidities, e.g. renal insufficiency. While new studies have helped to confirm proof of concept, the linkage to improved clinical outcomes is much less well-established and should be a focus of future research.

**Recommendations**

CTA shows considerable promise as a diagnostic modality for the two indications of current interest to CMS. The science base supporting its use is developing rapidly and will be considered by AHA in the routine review that all of our scientific statements and clinical guidelines undergo. That science base, however, remains incomplete and should, in our opinion be expanded, given its potential scope of application.
To contribute to a more complete database, our organization is a member of the workgroup convened by the Center for Medical Technology Policy to develop a randomized, controlled clinical trial that will “compare the clinical outcomes for patients at intermediate risk for CAD initially evaluated with CTA (versus those who receive) any alternative, conventional non-invasive” evaluation. Other participants in that planning process include federal agencies (Food and Drug Administration and AHRQ), large payers (Aetna, Kaiser Permanente, BCBSA and United Healthcare), the imaging industry (GE Healthcare, Siemens, Phillips Medical and Toshiba) and large academic institutions (Mayo Clinic). Primary endpoints include changes in 10-year Framingham risk scores and occurrence of major adverse cardiac events; secondary endpoints include post-test resource utilization, appropriateness of referrals for cardiac catheterization and total radiation dose. Studies with this rigor will help to compliment the work by Goldstein et al. cited above.

AHA supports the Agency’s decision to evaluate this procedure and consider implementing a national coverage determination. While local Medicare carriers currently have the option of providing coverage for CTA under a local coverage determination (LCD), coverage policies vary by carrier and a number of carriers have yet to adopt a LCD for CTA, leaving many Medicare beneficiaries without access to this procedure. A national coverage determination, on the other hand, would establish uniform coverage for CTA through an evidence-based process. We believe that new data of the type cited above, coupled with a consensus of expert opinion, is sufficient reason for CMS to consider creating a NCD for CTA. However, because the science base supporting use of CTA needs to be expanded, we recommend that the Agency consider providing coverage of this procedure through a Coverage with Evidence Development designation that would require collection and reporting of additional data as a condition of Medicare reimbursement.

It is an inescapable fact that new medical technologies are often introduced in a climate of intellectual uncertainty. CMS has the dual responsibility to ensure that the nation’s healthcare resources are invested wisely and that every patient for whom they are responsible receives that care that they need and deserve. In addition, the Agency has the opportunity to leverage those resources to promote quality of health care, a crucial component of which is development of a robust data base. We believe that this NCA, together with the resultant NCD that it informs, is likely to advance the public health.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at 202-785-7908 or via email at susan.k.bishop@heart.org.

Sincerely,

Daniel W. Jones, MD
President, AHA