Pennsylvania
CHAPTER

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Dear Ms. Dolfi:

On December 6, 2005 I was contacted by your office and asked to review Highmark's clinical policy on CT of the heart and CT angiography of the coronary and non-coronary vessels. Coincidentally, the Pennsylvania Chapter of the American College of Cardiology was contacted in an effort to obtain a brief position statement from the college on this imaging modality. As the current President of the Pennsylvania Chapter of the American College of Cardiology, I have drafted this letter in an effort to provide you with a response to your communications.

The American College of Cardiology (ACC) is a 33,000 member, non-profit professional medical society and teaching institution whose purpose is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines and to influence health care policy. The college represents more than 90% of the cardiologists practicing in the United States.

Recently, The American College of Cardiology Foundation in collaboration with the American Heart Association and the American College of Physicians created a task force on clinical competence relating to cardiac imaging with computed tomography and magnetic resonance. The intent of this document was to develop recommendations for obtaining and maintaining the cognitive and technical skills necessary for the competent performance of this new cardiovascular technology.

Computed tomography angiography is a non-invasive procedure that obtains volumetric images of blood vessels by using intravenously administered contrast material and high resolution, high speed computed tomography technology. Multi slice or multi-detective computed tomography with its advanced spatial and temporal resolution has created new possibilities in the imaging of the heart and major vessels of the chest including the coronary arteries.

Multi-detective computed tomography technology requires thin (up to 1 millimeter) slices, 0.5 to 0.75 millimeter reconstructions, multiple simultaneous images (e.g. 16, 32, 64 or more slices) and cardiac gaiting (often requiring beta-blockers for heart rate control). There is significant post processing, depending on the number of slices per second for image generation. The resultant coronary artery images show a high correlation with stenotic lesions noted on diagnostic cardiac catheterizations, but more importantly, with atheromas on intracoronary ultrasound.

CMS encourages the use of high-level evidence-based indications. New technology, however, often lacks the highest level of supporting evidence requiring the use of expert consensus in affording patient access to promising new technologies, which advance healthcare. As such, indirect evidence using diagnostic performance data, decision models and a consensus-based approach have been used to validate the current indications. We have anticipated that future additions and revisions to these baseline indications will occur as higher level evidence-based studies become available.

A number of trials published weekly regarding CTA supports the intent of the ACC to establish CTA as a technology that will improve net health outcomes. More than 100 trials for CTA were presented during the American Heart Association Annual Meeting in Dallas this past November and more than 100 CTA abstracts were submitted to the ACC for presentation at the upcoming ACC 2006 meeting in Atlanta, Georgia. It is anticipated that given this growing volume of studies that enough data will soon be available for proper evidence-based findings of this new non-invasive diagnostic test.

While Highmark currently classifies this procedure as experimental and investigational and not clinically accepted by the medical community, there is clearly a consensus among experts in the field that coronary CTA is a first-choice imaging technique and non-investigational for the examination of patients with suspected coronary artery disease, coronary anomalies or to define a specific course of treatment if anomalies are detected.

The American College of Cardiology additionally recommends the following indications in support of cardiac CTA:

(1) Coronary CTA is useful as first test to assess the cause of chest pain.
(2) Coronary CTA is useful as a triage tool to invasive coronary angiography following a stress test that is equivocal or suspected to be inaccurate.
(3) Coronary CTA is useful to evaluate the cause of symptoms in patients with known coronary artery disease.
(4) Coronary CTA is useful to evaluate the cause of chest pain or dyspnea in patients with prior bypass surgery or intracoronary artery stent placement.
(5) Coronary CTA is useful for suspected congenital anomalies of the coronary circulation.
(6) Coronary CTA is useful for evaluation of acute chest pain in the emergency room.
(7) CTA is useful for the assessment of coronary or pulmonary venous anatomy.
(8) Coronary CTA is useful to delineate coronary artery and graft anatomy prior to non-coronary artery surgery.

Over the past five months the ACC Carrier Advisory Committee has led a work group task force to develop a model LCD for cardiac computed tomography and computed tomography coronary angiography which is scheduled for completion by December 2005. The LCD work group represents a wide range of organizations including the American College of Radiology, the American Society of Nuclear Cardiology, the Society of Cardiac Angiography and Interventions, the Society of Cardiovascular Computed Tomography and several radiologists. Additional contributors include Aetna, United Health Care, Empire Blue Cross Shield Medicare Services and Wisconsin Physician Services.

Beginning January 1, 2006 the new category 3 CPT Codes for CCPA become effective and can provide assistance in examining the relevant patient population needed for cardiac CTA clarification. The college views this as an opportunity for collaboration with Medicare and other payers to implement a process to track utilization of this emerging technology which will in turn provide substantial and valuable data. It is the ACC's hope to partner with private payers to collect data and analyze CTA assessment. By tightly controlling who does the procedures with accurate training standards and specific indications, we invite Highmark to take the first step and load the ICD 9 codes for cardiac CTA-cardiac assessment so that together we may collect data and analyze outcomes based on patient demographics in our region.

The following answers are in response to the questions that were included in the initial contact dated December 6, 2005.

1. Is CT angiography of the coronary and non-coronary vessels considered to be beyond the experimental/investigational stage? Upon extensive review of the literature it is apparent that coronary CTA is a first choice imaging technique and not investigational for the examination of patients with suspected coronary artery disease, coronary anomalies or to define a specific course of treatment if anomalies are detected. Current available body of evidence demonstrates that coronary CTA can reliably rule out the presence of significant coronary artery disease in patients with a low to intermediate probability of having coronary artery disease and can reliably achieve a high degree of diagnostic accuracy and technical performance necessary to replace conventional coronary angiography. Information from cardiac CTA may be used to guide further diagnostic evaluations in addition to target appropriate therapy. For example, revascularization versus medical management and this may have a long-term influence on morbidity from coronary artery disease, functional status and mortality.

2. Is CT angiography of the coronary and non-coronary vessels accepted by the medical community as safe and effective procedures? With each new generation of CT scanner, diagnosis becomes more accurate and efficient. As a result, patients and clinicians benefit. Scanning speed as increased markedly. Today, a single image slice can be acquired in just 0.33 seconds; slice thickness of approximately 0.5 to 0.75 millimeters has become the norm. Higher resolution enables more detailed vascular mapping, more accurate stenosis measurement, better soft tissue detail, and optimization of data for 3D visualization across a range of tissue types. Moreover, radiation dose, which was once a focus of criticism, can be reduced by built in dose modulation software, or efficient detectors, and better detector design. One of the earlier studies of 64-coronary CT angiography reported an overall sensitivity for classifying stenosis of 94%, a specificity of 97%, a positive predicted value of 87% and a negative predicted value of 99% [Leschka, S.; Alkavhi, H.; Plass, A; et al Accuracy of MSCT Coronary Angiography with 64 Slice Technology: First Experience. European Heat Journal 2005, Volume 26, Pages 1482-1487].

3. What are the most common conditions, indications or applications for performing CT angiography of the coronary and non-coronary vessels? In addition to the assessment of coronary artery stenoses, MDCT angiography can successfully evaluate coronary artery aneurysm, cardiac tumors, bypass graft, congenital heart disease and many other cardiac conditions. The assessment of coronary stents by CT angiography is difficult and the results are variable. Whether the inside of the stent can be visualized depends on many factors including scanner technology, the size of the stent and the type of stent. Multi detective CT is an increasingly powerful tool for imaging thoracic aortic disease, pericardial disease, cardiac masses, valvular disease and non-ischemic myocardial disease.

4. Does CT angiography of the coronary and non-coronary vessels provide useful diagnostic information that is not attainable through other diagnostic studies such as conventional angiography, echocardiography, nuclear imaging procedures including SPECT? Coronary CTA may be used as a triage tool to invasive coronary angiography following a stress test that is equivocal or suspected to be inaccurate.

Coronary CTA might be chosen in select patients who have an equivocal or suspected inaccurate stress or stress imaging study. The rationale is that a non-invasive coronary anatomic test such as obtained by cardiac CT angiography might permit a separate method of assessing the coronary arteries which is different from a stress test and limits the number of normal invasive coronary angiograms. The use of coronary CTA may also be of benefit in evaluating the extent of coronary artery disease, which resulted in a prior cardiac event or symptom. Patients with known disease may have been evaluated in the past with prior invasive angiography and/or stress test. New or recurrent symptoms may or may not relate to a change in the coronary anatomy and could potentially be assessed with coronary CTA.

5. How do the outcomes of CT of the coronary vessels and non-coronary vessels compare to the outcomes of current standards of diagnosis and treatment planning? As mentioned earlier, data is currently being collected in an effort to study patient outcomes and results comparing cardiac CTA to other current standards of diagnosis. Coronary CTA would be useful to assess patients suspected of having congenital coronary anomalies. The cross-sectional nature of this technique allows one to definitively determine both the presence and possible future harm that could result from the anomaly. A coronary CTA may be used to decide if surgery is indicated and for surgical planning. In addition, coronary CTA is useful for evaluation of acute chest pain in the emergency room. The rationale for the application of coronary CTA in this setting is to quickly triage patients in order to rule out coronary artery disease as a possible cause of symptoms. Coronary CTA would be employed here because of its high negative predictive value. It is hoped that the application of coronary CTA in the emergency room would limit resource use in chest pain patients who do not have coronary artery disease. Another role of CT angiography would be for the assessment of coronary and pulmonary venous anatomy. The application of CTA for the coronary and pulmonary veins is primarily for pre-surgical planning. Coronary venous anatomy can be useful to the cardiologist who needs to place a pacemaker lead in the lateral coronary vein in order to resynchronize cardiac contraction in patients with heart failure. This may be helpful to identify ventricular pacemaker placement. Pulmonary vein anatomy can vary from patient to patient. Pulmonary vein catheter ablation can isolate electrical activity from the pulmonary vein and allow for the elimination of recurrent atrial fibrillation. The presence of a pulmonary venous anatomic map may help eliminate procedural complications and allow for the successful completion of the procedure. Also, the use of coronary CTA prior to non-coronary artery cardiac surgery would prove of benefit. Certain patients having non-coronary artery surgery, valve or ascending aortic surgery routinely have a pre-operative invasive coronary angiogram. The surgical planning may also depend on the exact location of the coronary artery. The rationale for the use of coronary CTA in these low risk patient subsets is to avoid potentially unnecessary invasive testing and still provide appropriate pre-surgical information.

6. Please cite any recent clinical publications that you believe would be helpful to us in this evaluation. I have enclosed a copy of the ACC/AHA Clinical Competent Statement on cardiac imaging with computed tomography and magnetic resonance. This is a report of the American College of Cardiology Foundation, the American Heart Association, and the American College of Physicians Task Force on clinical competence and training with these new imaging modalities.

Some potential limitations that should be considered with regard to this technology are the following:

1. The test is never covered for screening in the absence of signs, symptoms or disease.
2. The selection of the test should be made within the context of other testing modalities such as stress myocardial perfusion images or cardiac ultrasound results. The resulting information facilitates the management decision not merely as a new layer of testing.
3. Several challenges remain with this technology. It is difficult to image patients with dense coronary calcification. When there is a pre-test knowledge of sufficiently extensive calcification of the coronary segment in question, the interpretive value of the study is diminished.
4. Using the administration of beta-blockers and monitoring the patient during MDCT by a physician experienced in the use of cardiovascular drugs are essential in optimizing image acquisition.

I appreciate the opportunity to comment and would be available to review any questions relating to this technology.

Sincerely,

Steven M. Ettinger, M.D.
President, PA Chapter of the American College of Cardiology