



**BlueCross BlueShield
of Alabama**

Name of Policy:

Cardiac Computed Tomography (CCT), Cardiac Computed Tomography Angiography (CCTA)

Policy #: 230
Category: Radiology

Latest Review Date: December 2011
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Cardiac Computed Tomography (CCT) or Cardiac Computed Tomography Angiography (CCTA) is a noninvasive imaging test that requires the use of intravenously administered

contrast material and high-resolution, high-speed CT machinery to obtain detailed volumetric images of blood vessels or heart structure. To apply CCT/CCTA in the coronary arteries, several technical challenges must be overcome to obtain high-quality diagnostic images. First, very short image acquisition times are necessary to avoid blurring artifacts from the rapid motion of the beating heart. In some cases, premedication with beta-blocking agents is used to slow down the heart rate below about 60–65 beats per minute to facilitate adequate scanning, and electrocardiographic triggering or retrospective gating is used to obtain images during diastole when motion is reduced. Second, rapid scanning is also helpful so that the volume of cardiac images can be obtained during breath-holding. Third, very thin sections (<1 mm) are important to provide adequate spatial resolution and high-quality 3D reconstruction images.

Volumetric imaging permits multiplanar reconstruction (MPR) of cross-sectional images to display the coronary arteries. Curved MPR and thin-slab maximum intensity projections (MIPs) provide an overview of the coronary arteries, and volume-rendering techniques (VRT) provide a 3D anatomical display of the exterior of the heart. Quantification of coronary artery stenosis may be difficult given current techniques, although improvements in image reconstruction algorithms such as automatic vessel tracking are being developed.

Two different CT technologies can achieve high-speed CT imaging. Electron beam CT (EBCT, also known as ultrafast CT) uses an electron gun rather than a standard x-ray tube to generate x-rays, thus permitting very rapid scanning, on the order of 50–100 milliseconds per image. Helical CT scanning (also referred to as spiral CT scanning) also creates images at greater speed than conventional CT by continuously rotating a standard x-ray tube around the patient so that data are gathered in a continuous spiral or helix rather than individual slices. Helical CT is able to achieve scan times of 500 milliseconds or less per image and use of partial ring scanning or post-processing algorithms may reduce the effective scan time even further.

Multidetector row helical CT (MDCT) or multislice CT (MSCT) scanning is a technological evolution of helical CT, which uses CT machines equipped with an array of multiple x-ray detectors that can simultaneously image multiple sections of the patient during a rapid volumetric image acquisition. Currently available MDCT machines may have 4, 8, 16, 32, 40, or 64 detectors. Diffusion of MDCT machines into the medical community has been occurring over the past several years, although availability of 16 or more row CT imaging is still relatively limited.

Evaluation of obstructive coronary artery disease (CAD) involves quantifying arterial stenoses to determine whether hemodynamically significant stenosis is present. Symptomatic lesions with greater than 50%–75% diameter stenosis are generally considered significant and often result in revascularization procedures when viable myocardium is present. It has been suggested that CCT/CCTA may be helpful to rule out the presence of CAD and to avoid invasive coronary angiography in patients with a very low clinical likelihood of significant CAD. Also of note is the increasing interest in exploring the role of nonsignificant plaques (i.e., those associated with less than 50% stenosis) because it is postulated that some of these plaques that are considered unstable may undergo rupture or erosion and lead to acute myocardial infarction. Cross-sectional angiographic imaging may visualize the presence and composition of these plaques and quantify the plaque burden better than conventional angiography, which only visualizes the vascular

lumen. However, it is not yet well established how this information would be used to guide patient management.

The information sought from angiography after coronary artery bypass graft surgery may depend on the length of time since surgery. Bypass graft occlusion may occur during the early postoperative period; whereas, over the long term, recurrence of obstructive CAD may occur in the bypass graft, which requires a similar evaluation as CAD in native vessels.

Congenital coronary arterial anomalies (i.e., abnormal origination or course of a coronary artery) that lead to clinically significant problems are relatively rare lesions. Symptomatic manifestations may include ischemia or syncope. Clinical presentation of anomalous coronary arteries is hard to distinguish from other more common causes of cardiac disease; however, anomalous coronary artery is an important diagnosis to exclude, particularly in young patients who present with unexplained symptoms (e.g., syncope). There is no specific clinical presentation to suggest a coronary artery aneurysm.

CCT/CCTA has several important limitations. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory study. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

Also, it is important to consider the radiation dose associated with CCT/CCTA. Four-row MDCT with 1-mm sections delivers approximately 7.1 to 11.9 mSv and 16-row MDCT with 0.75-mm sections delivered approximately 8.8 mSv, whereas EBCT using ECG triggering delivers the lowest dose (approximately 0.7 to 1.1 mSv with 3-mm sections). In comparison, conventional invasive coronary angiography delivers about 4-8 mSv. It is hoped that use of modulation of the x-ray beam with MDCT may reduce dosage by reducing exposure during non-imaging phases of the cardiac cycle.

The use of electron beam CT to detect coronary artery calcification is addressed in a separate policy number 104.

Policy:

Effective for dates of service on or after December 28, 2011:

Contrast-enhanced computed tomographic angiography for the evaluation of patients without known coronary artery disease and acute chest pain in the emergency room/emergency department setting **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage. **See page 4, Evaluation #III for specific criteria.**

Cardiac Computed Tomography (CCT), Cardiac Computed Tomography Angiography (CCTA) using a 64-slice or greater CT scanner **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for any of the following conditions:

- I. Detection of CAD: Symptomatic
 - a. Evaluation of chest pain syndrome
 - i. Intermediate pre-test probability* of CAD and ECG uninterpretable or unable to exercise
 - b. Evaluation of intra-cardiac structures
 - i. Evaluation of suspected coronary anomalies
 - c. Acute chest pain
 - i. Intermediate pre-test probability* of CAD and no ECG changes and serial enzymes negative

- II. Detection of CAD with prior test results
 - a. Evaluation of chest pain syndrome
 - i. Un-interpretable or equivocal stress test (exercise, perfusion, or stress echo)

- III. Evaluation
 - a. Evaluation of acute chest pain in the Emergency Room/Emergency Department of the hospital for patients with low to moderate pre-test probability of CAD that meet all of the following criteria:
 - i. No known coronary artery disease;
 - ii. No elevated serum biomarkers including creatine kinase-myocardial band, myoglobin and/or troponin I;
 - iii. No ischemic EKG changes such as ST-segment elevation or depression $\geq 1\text{mm}$ in 2 or more contiguous leads, and or T-wave inversion $> 2\text{ml}$;
 - iv. No previously known cardiomyopathy with an estimated ejection fraction $\leq 45\%$.

- IV. Structure and Function
 - a. Morphology
 - i. Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves
 - ii. Evaluation of coronary arteries in patients with new onset heart failure to assess etiology
 - b. Evaluation of intra- and extra-cardiac structures
 - i. Evaluation of cardiac mass (suspected tumor or thrombus) and patients with technically limited images from echocardiogram, MRI or TEE
 - ii. Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery) and patients with technically limited images from echocardiogram, MRI or TEE
 - iii. Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation (e.g., pulmonary vein isolation)
 - iv. Non-invasive coronary vein mapping prior to placement of biventricular pacemaker or, **effective for dates of service on or after November 24, 2008**, placement of automatic implantable cardioverter defibrillator (AICD)

- v. Non-invasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization
- c. Evaluation of aortic and pulmonary disease
 - i. Evaluation of suspected aortic dissection or thoracic aortic aneurysm
 - ii. Evaluation of suspected pulmonary embolism

*Refer to Key Points for definition of pretest probability.

Contrast-enhanced computed tomographic angiography (CTA) of the coronary arteries **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage if performed for indications not listed above or when imaged with less than a 64-slice CT scanner.

Computed tomography, heart, without contrast material including image post-processing and quantitative evaluation of coronary calcium **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage when a CCT or CCTA meets the coverage criteria noted above, but when a review of the initial non-contrast CT images is reviewed it is determined that based on the calcium volume the patient is not a candidate for the arterial phase component of the study. (In this case only code ~~0144F~~ 75571 should be reported.)

The evaluation of calcium volume as a stand alone test **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

The following are contraindications to CCT/CCTA:

- Irregular rhythm (e.g., atrial fibrillation/flutter, frequent irregular premature ventricular contractions or premature atrial contractions, and high grade heart block).
- Very obese patients, body mass index > 40 kg/m².
- Renal insufficiency, creatinine > 1.8 mg/dl.
- Heart rate > 70 beats/minute refractory to heart-rate lowering agents (e.g., a combination of beta-blocker and calcium-channel blocker)
- Metallic interference (e.g., surgical clips, pacemaker, and/or defibrillator wires, or tissue expander)
- Calcium score > 1,000

Effective for dates of service on or after February 1, 2007 and prior to December 28, 2011:

Cardiac Computed Tomography (CCT), Cardiac Computed Tomography Angiography (CCTA) using a 64-slice or greater CT scanner **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for any of the following conditions:

- I. Detection of CAD: Symptomatic
 - a. Evaluation of chest pain syndrome
 - i. Intermediate pre-test probability* of CAD and ECG uninterpretable or unable to exercise
 - b. Evaluation of intra-cardiac structures

- i. Evaluation of suspected coronary anomalies
 - c. Acute chest pain
 - i. Intermediate pre-test probability* of CAD and no ECG changes and serial enzymes negative
- II. Detection of CAD with prior test results
 - a. Evaluation of chest pain syndrome
 - i. Un-interpretable or equivocal stress test (exercise, perfusion, or stress echo)
- III. Structure and Function
 - a. Morphology
 - i. Assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves
 - ii. Evaluation of coronary arteries in patients with new onset heart failure to assess etiology
 - b. Evaluation of intra- and extra-cardiac structures
 - i. Evaluation of cardiac mass (suspected tumor or thrombus) and patients with technically limited images from echocardiogram, MRI or TEE
 - ii. Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery) and patients with technically limited images from echocardiogram, MRI or TEE
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The evaluation of calcium volume as a standalone test **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

The following are contraindications to CCT/CCTA:

- Irregular rhythm (e.g., atrial fibrillation/flutter, frequent irregular premature ventricular contractions or premature atrial contractions, and high grade heart block).
- Very obese patients, body mass index > 40 kg/m².
- Renal insufficiency, creatinine > 1.8 mg/dl.
- Heart rate > 70 beats/minute refractory to heart-rate lowering agents (e.g., a combination of beta-blocker and calcium-channel blocker)
- Metallic interference (e.g., surgical clips, pacemaker, and/or defibrillator wires, or tissue expander)
- Calcium score > 1,000

Effective for dates of service prior to February 1, 2007:

Cardiac Computed Tomography (CCT), Cardiac Computed Tomography Angiography (CCTA) **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was originally based on a literature search conducted on MEDLINE via PubMed through February 2004 and updated with a February 2005 TEC Assessment. The objective of the TEC Assessment was to evaluate the clinical effectiveness of contrast-enhanced cardiac computed tomography angiography (CTA) using either electron beam computed tomography (EBCT) or multidetector-row computed tomography (MDCT) as a noninvasive alternative to invasive coronary angiography (CA), particularly in patients with a low probability of significant coronary artery stenosis. Evaluation of the coronary artery anatomy and morphology is the most frequent use of cardiac CTA and was the primary focus of the TEC Assessment. Cardiac CTA may also provide evaluation of the cardiac chambers, myocardial wall thickness, and functional evaluation of the heart including perfusion patterns of enhancement and estimation of ejection fraction, but this use was not addressed in this Assessment.

The TEC Assessment concluded that the use of contrast-enhanced cardiac CT angiography for screening or diagnostic evaluation of the coronary arteries did not meet TEC criteria. The following summarizes the findings from the 2005 TEC Assessment.

Screening for CAD

No eligible studies were identified using contrast-enhanced CTA as a screening test for CAD in asymptomatic subjects or among subjects planned for major noncardiac surgery.

Diagnosis of CAD (Acute)

One small study examined the use of CTA in 22 hospitalized patients with non-ST elevation acute coronary syndromes who were scheduled for CA. CTA yielded evaluable images of vessel segments >2 mm in diameter in 98% of cases and achieved 94% sensitivity, 96% specificity, 99% negative predictive value, and 77% positive predictive value for stenosis >50% compared with conventional angiography. The study also suggested that if CTA had been used for initial evaluation in place of CA, 3 patients (14%) with no significant CAD might have been spared CA. The very high NPV in this small study is of interest, but this would need to be confirmed in additional large prospective studies.

Kuettner et al in the Journal of the American College of Cardiology article of January, 2005 addresses this question. "...Although MDCT imaging is becoming more accurate, a complete visualization of the entire coronary tree can still not be expected, and further technical improvements are required until (sic) MDCT might challenge ICA as reference imaging modality in patients with suspicion of CAD...Limitations of MDCT are radiation exposure...the need for iodinated contrast agents, and the fact that reduction in heart rate using beta-blockade is still recommendable (sic)...In conclusion, MDCT imaging is becoming more and more accurate. However, further improvements of spatial and temporal resolution are still required to challenge diagnostic invasive coronary angiography."

Mollet et al reported "...MSCT will not equal either the resolution or real-time imaging capabilities of conventional CA in the foreseeable future..." The authors also touch on the persistent issues related to radiation doses in excess of conventional coronary arteriography (11.8-16.3 mSv compared to 3-5 mSv) and partial voluming and artifacts related to coronary calcifications. These lead to false positive findings.

Diagnosis of CAD (Non-acute)

There are 14 studies (total n=723) reporting the diagnostic performance characteristics of CTA for evaluation of nonacute, symptomatic patients with known or suspected CAD who are scheduled for invasive CA. Most studies were prospective, double-blinded, and used conventional angiography as the reference standard. The results for CTA were variable with technical success in achieving evaluable vessels between 79% and 93% for MDCT and 77% and 89% for EBCT. It is important to consider the patient as the unit of analysis, and 1 study that provided this information found that 74% of patients had all vessels evaluable on CTA. This implies that approximately one fourth of subjects undergoing MDCT may have at least some limitation in the visualization of the coronary arteries.

Within the 11 studies using MDCT (total n=622), 4 studies (total n=289) reported patient-based analyses, CTA achieved 85%–100% sensitivity, 78%–86% specificity, 81%–97% positive predictive value, and 75%–100% negative predictive value. It is important to recognize that the higher sensitivity estimates in these ranges addressed only segments >2mm in diameter. A larger

number of studies provide vessel- or vessel segment-based analyses reporting sensitivity ranging from 63%–95%, specificity 86–98%, positive predictive value 64%–87%, and negative predictive value (NPV) 96%–99%. This NPV is frequently reported as being high enough to exclude the diagnosis of significant stenoses; however, this analysis addresses vessels/segments and decisions to avoid invasive angiography are not based on a per vessel analysis. Furthermore, the prevalence of significantly stenotic vessels is only 10%–37%, which will make the NPV appear higher than if CTA were analyzed at the patient level where there is a higher prevalence of significant CAD with all vessels summed together. These vessel/segment-based analyses may be useful in determining treatment decisions about single vessels, but are not the most useful analyses when making treatment decisions about the patient as a whole. Thus, to exclude the diagnosis of CAD and avoid the need for invasive angiography, the negative predictive value for the patient based on all the coronary arteries is the relevant information.

Among the studies using EBCT (total N=101), all 3 studies report diagnostic performance based on vessels or segments with a prevalence of stenotic vessels/segments of 15%–21%. Sensitivity range was 70%–77%, specificity was 91%–95%, NPV was 95%, and PPV was 70%–73%.

Diagnosis after CABG

One prospective study examined the use of MDCT in 48 patients who were scheduled for CA after CABG. After excluding 3 technical failures, the authors report technical success in visualizing 100% of bypass grafts and 74% of distal anastomoses. Sensitivity, specificity, and positive and negative predictive values for graft occlusion were 96%, 95%, 81%, and 99%, respectively. However, this study provides no information about patient symptoms or how evidence of graft occlusion would affect management.

Diagnosis of CAD after stent

Two small studies (1 MDCT and 1 EBCT) have examined the feasibility of using CTA for evaluation shortly after stent placement and found 74% to 87% of stents evaluable. However, these small studies were very limited in reporting, did not examine subjects with suspicion of clinically recurrent CAD, and did not use double-blinded assessment.

Delineation of coronary artery anomaly

Two small studies including a total of 29 subjects, who were all selected for study based on a known or suspected coronary artery anomaly, suggest that CTA may provide a better evaluation of anomalous arterial anatomy than conventional coronary angiography. However, both studies were retrospective and neither prospectively evaluated the diagnostic performance of CTA in evaluating unknown consecutive clinical cases.

Delineation of coronary artery anatomy prior to cardiovascular procedure

One small study reports that it is feasible to delineate coronary venous anatomy based on simultaneous coronary arterial and venous enhancement on EBCT. Another recently published study examined the predictive value of CTA in 45 patients with chronic total coronary occlusions who were scheduled for percutaneous revascularization. Results of multivariable logistic regression were reported, but performance characteristics for CTA such as sensitivity, specificity, and positive and negative predictive value for procedural failure are not reported.

Thus, these results are not sufficient to determine the effect of using CTA on management and health outcomes.

In summary, the TEC Assessment found that the available evidence does not provide sufficient information to permit conclusions on the effect of CTA on health outcomes. Available studies are limited by small sample size, single-center design, possible overlap of patient populations with duplicate reporting, failure to enroll clinically relevant patient population, variable technical success rates for CTA, inconsistent analysis of diagnostic performance characteristics, reporting of diagnostic performance limited to evaluable segments, failure to report diagnostic performance per patient, and, most importantly, the inability to translate diagnostic performance of CTA to expected effects on management and health outcomes. Furthermore, as referenced by Raff, et al, “future studies are necessary to determine whether present-generation MSCT scanners have sufficient resolution to delineate complex and unstable lesions”.

Despite the promising results of the clinical studies, there remain several important limitations which must be considered. First, in the study by Hoffmann, the average dose used was 8.1 msv for 75kg patient. This dose is equivalent to 2-3 times the dose typically administered during the diagnostic invasive angiogram. Although, the risk associated with this level of radiation exposure is relatively low, it does raise concerns about the repeat use of this type of testing in younger individuals and women of child-bearing age.

Another study by Cole, et al, performed a comparison of radiation doses from multislice computed tomography coronary angiography and conventional diagnostic angiography. A CTA with an effective dose of 14.7 mSv has a risk of approximately inducing a fatal cancer in 1 of 1,400 while the conventional coronary angiogram at 5.6 mSv has a risk of 1 in 3,600. This article concludes that the clinical role of non-invasive CTA should take into account that the amount of ionizing radiation should be justified and optimized.

Second, the test is limited by the extent and severity of coronary calcification in the population which may be studied. In addition, in-stent visualization is either not feasible or is inaccurate in a lot of the cases depending on the machine used for the scanning. There is limited evidence to suggest that this type of scanning could be useful for individuals with stents or status-post coronary bypass surgery.

There remain technological challenges related to temporal resolution for individuals who do not have stable or regular heart rates. Although it is likely this will rapidly improve with technological advances, at the present time this type of imaging should be avoided in patients whose resting heart rate exceeds 80 bpm even after administration of negative chronotropic drugs. Finally, image resolution may be compromised by body habits in individuals who are obese. This represents an increasing number of individuals who may be considered for this type of imaging. Finally, addition outcome studies will likely address the limitations and help to more clearly outline the role of coronary angiography in clinical practice.

In February 2006, the AHA Science Advisory issued a statement on the utilization of Cardiac Imaging. The statement issued principles to be used in the development and use of existing and emerging cardiac imaging modalities. Included in the principles are that rigorous scientific

research should continue to critically exam these emerging modalities and define their advantages and limitations.

Since the February 2005 TEC Assessment, there have been several articles published on the improved accuracy of the 16-, 40-, and 64-slice computed tomographic scanners. All of these studies compared multidetector computed tomography to invasive coronary angiography. The sample sizes were small, but the results were improved. Some of the articles are summarized below.

Cury et al (2005), looked at the accuracy of 16-slice MDCT as compared to quantitative coronary angiography in 29 patients (42 sites). The correlation between MDCT and QCA for quantifying the degree of stenosis was excellent ($r^2 = 0.93$), although a systematic overestimation was observed by MDCT (bias 4% to 8%). The correlation between MDCT and QCA was moderate with respect to lesion length ($r^2 = 0.54$). They concluded that MDCT permits non-invasive quantification of coronary stenosis in the absence of severe calcifications or motion artifacts.

Lim et al (2006) looked at the accuracy of multi-section computed tomography (MSCT) using a 40-section multidetector row machine as compared with invasive coronary angiography to detect significant coronary stenosis. A total of 480 segments from 30 patients were analyzed. 94 segments (20.4%) showed significant ($\geq 50\%$) stenosis by invasive coronary angiogram. Accuracy results for MSCT showed 99% sensitivity, 98% specificity, 94% PPV, and 99% NPV. The authors concluded that in a small select group of patients, MSCT is as reliable as coronary angiography in detecting significant obstructive CAD.

Fine et al (2006) looked at the accuracy of 64-slice cardiovascular tomography (CVCT) in relation to direct catheter coronary angiography. They looked at 66 patients (50% with chest pain) who underwent both procedures within 30 days. Accuracy results were 94% for interpretable images, 95% for sensitivity, 96% for specificity, 97% for PPV, and 92% for NPV. The CVCT and catheter angiography showed 98% accuracy for the left main CA and 93% accuracy for the LAD CA. The authors concluded that the 64-slice CVCT was more accurate than the 16 slice generation to identify significant atherosclerotic lesions.

Ropers et al (2006) looked at the accuracy of 64-slice MDCT compared to quantitative coronary angiography to detect significant coronary artery stenoses. 84 patients with suspected CAD had MDCT, then invasive coronary angiography 1 to 3 days later. Of 1083 evaluable segments, MDCT showed 93% sensitivity, 97% specificity, 100% NPV. Of 321 evaluable arteries, MDCT showed a 95% sensitivity and 93% specificity. The authors noted that severe calcium deposits remain a limitation of this method.

Schuijf et al (2006), looked at the accuracy of 64-slice MSCT to detect significant coronary artery disease ($\geq 50\%$ luminal narrowing) in patients scheduled for conventional coronary angiography. In 60 patients, there were 854 segments available for evaluation. Conventional coronary angiography identified 73 lesions, of which 62 were detected by MSCT. The results showed MSCT had a sensitivity of 85% and a specificity of 97%. On a patient-per-patient analysis, the results showed 94% sensitivity, 97% specificity, 97% positive predictive value, and

93% negative predictive value. The authors concluded that 64-slice MSCT enables the accurate and non-invasive evaluation of significant coronary artery stenoses.

Multidetector computed tomography (MDCT) provides advanced spatial and temporal resolution of the heart and allows imaging of the major vessels of the chest, including the coronary arteries. The new 64-slice sub-millimeter thin slice detectors CT scanners seem to be more accurate than previous 16-slice scanners, with NPV approaching 99% for coronary artery studies.

In summary, MDCT studies performed on scanners with sub-millimeter slice thickness and at least 16 detectors/rotation yield useful diagnostic information about cardiac structure and morphology, function, ejection fraction, and wall motion. CCTA studies performed on scanners with sub-millimeter slice thickness and at least 32 detectors/rotation yield useful diagnostic information about native and anomalous coronary arteries and coronary bypass grafts. MDCT and CCTA are non-invasive tools which may be used to evaluate patients with suspected coronary artery disease, and may provide a negative predictive value which is sufficient to avoid invasive coronary angiography. These studies also yield valuable clinical information in patients with suspected congenital cardiac anomalies.

In a recent study by Einstein, et al, estimating the risk of cancer associated with radiation exposure from 64-slice CTCA, it concluded that CCTA should be used cautiously in the evaluation of young individuals, especially women. In this study, the lifetime risk for cancer from a single CTCA for women was 1 in 143 at age 20, 1 in 284 at age 40, and 1 in 466 at age 60. Lung and breast cancer accounted for 80% of the cancer risk. The men's risk calculated lower at 1 in 686 at age 20, 1 in 1,007 at age 40 and 1 in 1,241 at age 60. The women's higher risk was attributed to greater radiosensitivity of their lungs and the fact that the breast lies in the field of irradiation during the CTCA.

Baliga et al in a 2007 article in Journal of Nuclear Cardiology state, "High radiation exposure with CT angiography (CTA) call into question the escalating use of the technology as an alternative to conventional coronary angiography. Using CTA as the first step in evaluating suspected coronary artery disease would almost triple the radiation exposure in patients with confirmed coronary artery disease compared with conventional angiography as the initial approach....With coronary angiography as the initial test, the 527 patients with exposed to an average radiation dose of 7.5mSv. With CTA as the initial imaging modality, patients with normal coronary arteries (N=231) would have been exposed to 11.0 mSV of radiation."

Among patients with abnormal CTA results (N=296), follow-up coronary angiography would have increased the radiation exposure to 19.2 mSv.

The American College of Cardiology Foundation, along with key specialty and subspecialty societies, reviewed the appropriateness of two relatively new clinical cardiac imaging modalities, cardiac computed tomography (CCT) and cardiac magnetic resonance (CMR) imaging. The reviews assessed the risks and benefits of imaging tests for several indications or clinical scenarios and scored them on a scale of 1 to 9, with the upper range (7-9) implying that the test is generally acceptable and a reasonable approach for the indication. Computed tomographic angiography, while very promising with regard to the detection of "soft plaque", assessment of

left ventricular function and congenital coronary anomalies, and evaluation of cardiac structures has limited data supporting its use for many clinical applications especially with regard to its role within patient care algorithms.

The indications contained in the report are not exhaustive. For example, the use of CCT or CMR for the non-invasive evaluation of coronary arteries before non-coronary cardiac surgery was not listed as an indication, although this may be an evolving application. There may be medical reasons that would preclude the application of the appropriateness criteria to a specific patient. This report also included several assumptions for CCT. The cardiac computed tomography equipment and personnel have the minimal technical capabilities required for the indication (the number of detector rows, spatial and temporal resolution, and acquisition protocols). For this policy, a 64-slice CT scanner is required. The use of the test to determine non-cardiac etiologies for an indication are not considered.

Definitions and Processes for Determining Likelihood of Disease and Risk

Determining Pre-Test Risk Assessment for Risk Stratification

Coronary Heart Disease (CHD) Risk*

CHD Risk—Low

Defined by the age-specific risk level that is below average. In general, low risk will correlate with a 10-year absolute CHD risk less than 10%

CHD Risk—Moderate*

Defined by the age-specific risk level that is average or above average. In general, moderate risk will correlate with a 10-year absolute CHD risk between 10% and 20%.

CHD Risk—High*

Defined as the presence of diabetes mellitus in a patient ≥ 40 years of age, peripheral arterial disease or other coronary risk equivalents or the 10-year absolute CHD risk of greater than 20%.

Blue Cross and Blue Shield of Alabama considers the presence of Diabetes Mellitus will place all members in the high risk group.

Determination of Pre-test Probability for obstructive/significant Coronary Disease Based on Chest Pain

Chest Pain Syndrome: any constellation of symptoms that the physician feels may represent a complaint consistent with obstructive CAD. Examples of such symptoms include, but are not exclusive to: chest pain, chest tightness, burning, dyspnea, shoulder pain, and jaw pain.

Pre-Test Probability of CAD: Once the physician determines the presence of symptoms that may represent obstructive CAD, then the pre-test probability of CAD should be determined.

Although there are several methods for determining pre-test probability of CAD, readers should refer to the American college of Cardiology/American Heart Association (ACC/AHA) 2002

Guideline Update for Exercise Testing and ACC/AHA 2002 Guideline Update for management of Patients with Chronic Stable Angina for definitions of angina:

- **Typical Angina (Definite):**
 - Substernal chest pain or discomfort that is provoked by exertion or emotional stress and relieved by rest and/or nitroglycerin.
- **Atypical Angina (Probable):**
 - Chest pain or discomfort that lacks one of the characteristics of definite or typical angina.
- **Non-Anginal chest Pain:**
 - Chest pain or discomfort that meets one or none of the typical angina characteristics.

CHART 1

The following assessment is used to determine pre-test probability of coronary artery disease based on description of the character of chest pain, member age and sex. This assessment will define the chest pain as typical angina, atypical angina, and non-anginal chest pain. This description then is applied to the age/sex criteria as follows:

Pre-test Probability of CAD by Age, Gender and Symptoms

Age Years	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
30-39	Men	Intermediate	Intermediate	Low	Very Low
	Women	Intermediate	Very Low	Very Low	Very Low
40-49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very Low	Very Low
50-59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very Low
≥ 60	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low
High: Greater than 90% pre-test probability		Intermediate: Between 10% and 90% pre-test probability	Low: Between 5% and 10% pre-test probability	Very Low: Less than 5% pre-test probability	
<p>Typical angina (definite): 1) Substernal chest pain or discomfort is 2) provoked by exertion or emotional stress and 3) relieved by rest and/or nitroglycerin.</p> <p>Atypical angina (probable): Chest pain or discomfort that lacks one of the characteristics of definite or typical angina.</p> <p>Non-anginal chest pain: Chest pain or discomfort that meets one or none of the typical angina characteristics.</p>					

CHART 2

Framingham Risk Assessment for Coronary Artery Disease

Framingham risk assessment is a calculation to predict the 10-year risk of heart disease in an individual member. The calculation is made from member age, sex, most recent lipid values and blood pressure, as well as smoking history and presence of diabetes. A sample calculator can be found online at:

<http://www.intmed.mcw.edu/clinical/heartrisk.html>

CHD Risk Level	Framingham Score
Low	Less than 10%
Moderate	Between 10% and 20%
High	Greater than 20%

*Based on the Framingham Risk Score calculation which can be found online at the National Heart, Lung, and Blood Institute Web site: <http://www.nhlbi.nih.gov/about/framingham/riskabs.htm>
<http://www.framinghamheartstudy.org/risk/index.html>

ECG—Un-interpretable

Refers to ECGs with resting ST-segment depression (greater than or equal to 0.10 mV), complete left bundle branch block, pre-excitation (Wolf-Parkinson-White syndrome), or paced rhythm.

The number of Computer Tomography (CT) scanners continues to increase as well as the usage of those scanners. It is estimated that more than 62 million CT scans per year are currently done in the United States, including at least 4 million children.

Conventional radiography doses of radiation are much smaller than CT; an abdominal CT delivers about 50 times more radiation to the stomach than conventional x-ray. Data has been gathered on the correlating radiation exposure and subsequent cancer rates from the Japanese survivors of atomic bombs, it is estimated by Brenner and Hall that 1.5% to 2.0% of cancers in the U.S. could be attributable to CT radiation. One study is now underway to gather direct data on CT-associated cancer with results not being available for some years. Per the December 6, 2007, Journal Watch, a recent survey suggested that many physician are unaware of radiation doses and potential risks associated with CT. (Radiology 2004; 231:393)

2011 Update

Two randomized controlled trials (RCTs) and two prognostic studies conducted in emergency settings were identified. The first evaluated 197 randomized patients from a single center without evidence of acute coronary syndromes to coronary CTA (n=99) or usual care (n=98). Over a 6-month follow-up, no cardiac events occurred in either arm. Invasive coronary angiography rates were somewhat higher in the coronary CTA arm (12.1% vs. 7.1%). Diagnosis was achieved more quickly following coronary CTA. The CT-STAT trial evaluated a similar sample of 699 randomized patients from 16 centers—361 undergoing coronary CTA and 338 myocardial perfusion imaging (MPI). Over a 6-month follow-up, there were no deaths in either arm, 2 cardiac events in the coronary CTA arm and 1 in the perfusion imaging arm. Invasive coronary angiography rates were similar in both arms. A second non-invasive test was obtained more often following coronary CTA (10.2% versus 2.1%), but cumulative radiation exposure in the

coronary CTA arm (using retrospective gating) was significantly lower—mean 11.5 versus 12.8 mSv. Time to diagnosis was shorter (mean 3.3 hours) and estimated emergency room costs lower with coronary CTA.

Two prognostic studies reported no cardiac events following a negative coronary CTA in the emergency room after 12 months' (n=481) and 24 months' (n=368) follow-up.

Radiation Exposure

Exposure to ionizing radiation increases lifetime cancer risk. Three studies have estimated excess cancer risks due to radiation exposure from coronary CTA. Assuming a 16-mSv dose, Berrington de Gonzalez et al estimated that the 2.6 million coronary CTAs performed in 2007 would result in 2,700 cancers or approximately 1 per 1,000. Smith-Bindman et al estimated cancer would develop in 1 of 270 women and 1 of 600 men age 40 undergoing coronary CTA with a 22-mSv dose. Einstein et al employed a standardized phantom to estimate organ dose from 64-slice coronary CTA. With modulation and exposures of 15 mSv in men and 19 mSv in women, the calculated lifetime cancer risk at age 40 was 7 per 1,000 men (1 in 143) and 23 per 1,000 women (1 in 43). However, estimated radiation exposure used in these studies is considerably higher than received with current scanners—now typically under 10 mSv and often less than 5 mSv with contemporary machines and radiation reduction techniques. For example, in the 47-center PROTECTION I study enrolling 685 patients, the mean radiation dose was 3.6 mSv, using a sequential scanning technique.

Although indirectly related to coronary CTA, Eisenberg et al analyzed administrative data from 82,861 patients undergoing imaging or procedure accompanied by radiation between April 1996 and March 2006 with 12,020 incident cancers identified. Based on estimated radiation exposures accompanying various cardiac imaging and procedures, over 5 years, there was an increased relative hazard for cancer of 1.003 per mSv (95% confidence interval [CI]: 1.002-1.004).

Summary

In patients presenting to emergency settings with acute chest pain that is possibly cardiac in origin and no known history of CAD, the net health outcome following coronary CTA appears at least as good as that obtained following other noninvasive testing strategies. CTA can rule out active coronary disease with a high rate of certainty in patients with low to moderate pre-test probabilities of CAD, and is an efficient strategy in the emergency setting. Therefore, CTA may be considered medically necessary for use in this patient population.

When anomalous coronary arteries require evaluation in symptomatic patients, coronary CTA also is likely to be beneficial in the setting of equivocal or unsuccessful invasive angiography. It has been demonstrated that CTA can define the anatomy of anomalous vessels when angiography is equivocal. Thus, CTA may be considered medically necessary for evaluating anomalous coronary arteries.

Key Words:

Computed tomography angiography, CTA, CT angiography

Approved by Governing Bodies:

Not applicable

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

BellSouth/AT&T contracts: No special consideration

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Special benefit consideration may apply. Refer to member’s benefit plan.

Wal-Mart: Special benefit consideration may apply. Refer to member’s benefit plan.

Pre-certification requirements: Effective for dates of service on or after November 1, 2007,

required when ordered by a provider in a Blue Cross and Blue Shield of Alabama’s Preferred or Participating Network for a patient covered by Blue Cross and Blue Shield of Alabama who will receive outpatient imaging services(s) from a Preferred Medical Doctor (PMD) or Preferred Radiology Participating (PRP) provider ~~for dates of service on or after November 1, 2006.~~

Exceptions to the Alabama PMD and PRP pre-certification requirement: NASCO, Wal-Mart, Blue Advantage, Flowers Foods, Inc., FEP.

In addition to the above Blue Cross and Blue Shield of Alabama PMD/PRP Network requirement, **some self-insured national account groups** may require pre-certification for all MRIs **effective for dates of service on or after January 1, 2009.** Please confirm during your benefit verification process if a pre-certification is required.

Reviews to verify accuracy of pre-certification information will be conducted.

Pre-determination requirements: Pre-determinations will be performed as a courtesy review at the request of the physician and/or subscriber.

Coding:

HCPCS: ~~S8093 — Computed tomographic angiography, coronary arteries, with contrast material(s) (Code deleted effective April 1, 2006)~~

Effective for dates of service on or after January 1, 2010:

- 75571 Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
- 75572 Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)

- 75573 Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure, and function and evaluation of venous structures, if performed)
- 75574 Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

Effective for dates of service on or after January 1, 2008:

- ~~0145T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; cardiac structure and morphology **(Code deleted effective January 1, 2010)**~~
- ~~0146T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**~~
- ~~0147T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**~~
- ~~0148T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**~~
- ~~0149T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**~~
- ~~0150T — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; cardiac structure and morphology in congenital heart disease **(Code deleted effective January 1, 2010)**~~

~~0151T~~ — Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing, function evaluation (left and right ventricular function, ejection fraction and segmental wall motion) (list separately in addition to code for primary procedure) **(Code deleted effective January 1, 2010)**

Effective for dates of service on or after January 1, 2007:

~~0151T~~ — Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3d image postprocessing, function evaluation (left and right ventricular function, ejection fraction and segmental wall motion) (list separately in addition to code for primary procedure) **(Code deleted effective January 1, 2010)**

Effective for dates of service on or after January 1, 2006:

~~0144T~~ — Computed tomography, heart, without contrast material, including image post processing and quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**

~~0145T~~ — Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3d image post processing; cardiac structure and morphology **(Code deleted effective January 1, 2010)**

~~0146T~~ — Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts); without quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**

~~0147T~~ — Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**

~~0148T~~ — Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**

~~0149T~~ — Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium **(Code deleted effective January 1, 2010)**

~~0150T~~ — Cardiac structure and morphology in congenital heart disease **(Code deleted effective January 1, 2010)**

~~0151T~~ — Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3d image post processing; function evaluation (left and right

~~ventricular function, ejection fraction and segmental wall motion)~~
(Code deleted effective January 1, 2010)

Providers should NOT use the CT of chest codes to report CCT/CCTA.

CPT code: **71275** Computed tomographic angiography, chest, without contrast material(s), followed by contrast material(s) and further sections, including image post-processing

Effective for dates of service on or after January 1, 2008:

71275 Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing

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Policy History:

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Medical Policy Group, December 2008 (3)

Medical Policy Administration Committee, December 2008

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Medical Policy Group, March 2011 (2) Web site and reference update

Medical Policy Group, November 2011 (3); Updated: Policy section to include medically necessary indications for acute chest pain in low or intermediate risk patients in the emergency room setting, Key Points, References

Medical Policy Administration Committee, November 2011

Available for comment November 11 through December 27, 2011

Medical Policy Group, December 2011 (1)

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.