DRAFT

BlueCross BlueShield of Alabama

Name of Policy:

Contrast-Enhanced Computed Tomographic Angiography (CTA) for Coronary Artery Evaluation

Policy #: 230
Category: Radiology

Latest Review Date: June 2005
Policy Grade: C

Background:

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.*

Coding:

HCPCS:	**S8093**	Computed tomographic angiography, coronary arteries, with contrast material(s)

Providers should NOT use the CT of chest codes to report this.

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

ICD-9:	**414.00**	Coronary atherosclerosis of unspecified type of vessel, native or graft
	414.01	Coronary atherosclerosis of native coronary artery
	414.02-414.05	Coronary atherosclerosis of bypass graft, code range

Description of Procedure or Service:

Contrast-enhanced computed tomographic angiography or CTA 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. CTA can be applied to image blood vessels throughout the body; however, to apply CTA 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 (<1mm) 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 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 CTA 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.

CTA 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 CTA. Four-row MDCT with 1-mm sections delivered 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 a 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 or helical CT to detect coronary artery calcification is addressed in a separate policy number 104.

Policy:

Contrast-enhanced computed tomographic angiography for coronary artery evaluation **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

The purpose of Blue Cross and Blue Shield of Alabama's medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

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. (1) 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 used 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.

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 contracts: No special consideration
FEP contracts: No special consideration
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification requirements: Not applicable
Pre-determination requirements: Pre-determinations will be performed as a courtesy review at the request of the physician and/or subscriber.

References:

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Policy History:

Medical Policy Group, June 2005 **(3)**
Medical Policy Administration Committee, July 2005
Available for comment July 28-September 10, 2005
