

SUBJECT: CARDIAC COMPUTED TOMOGRAPHIC ANGIOGRAPHY (CARDIAC CTA): CONTRAST-ENHANCED
POLICY NUMBER: 6.01.34
CATEGORY: Technology Assessment

EFFECTIVE DATE: 06/16/05
REVISED DATE: 09/21/06, 09/20/07, 09/18/08, 09/17/09, 06/17/10, 06/16/11, 07/19/12, 10/17/13, 06/19/14

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

1. Based upon our criteria and review of the peer-reviewed literature, cardiac computed tomographic angiography (CTA), using at least a 64-slice CT scanner, is considered **medically appropriate** for any of the following:
 - A. Cardiac CT for structure and morphology:
 1. Evaluation of native or prosthetic valve, cardiac mass, or pericardial mass and/or pericardial disease:
 - a. A prior cardiac CT angiogram, cardiac MRI or echocardiogram was performed for this indication and was uninterpretable.
 2. Pre-procedural preparation and structural assessment of patients being considered for Transcatheter Aortic-Valve Implantation (TAVI).
 3. Coronary vein mapping:
 - a. Biventricular pacemaker placement is planned.
 4. Coronary artery bypass graft localization:
 - a. Thoracic or cardiac surgery is planned.
 5. Pulmonary vein evaluation:
 - a. Radiofrequency ablation for atrial fibrillation is planned.
 6. Left ventricular function evaluation:
 - a. Congestive heart failure or a myocardial infarction within the last 4 weeks and an echocardiogram, cardiac MRI, or MUGA was performed but was uninterpretable.
 7. Quantitative right ventricular function evaluation:
 - a. An echocardiogram, cardiac MRI, or MUGA was performed but was uninterpretable.
 8. Suspected arrhythmogenic right ventricular dysplasia (ARVD)
 - a. ARVD is suspected because of documentation of greater than 1000 ventricular contractions per day, ventricular tachycardia, family history of ARVD or epsilon waves on the electrocardiogram AND no cardiac MRI has been performed (e.g., there is a contraindication to MRI) or cardiac MRI was performed and uninterpretable.
 - B. Cardiac CT for congenital heart disease:
 1. Coronary artery anomaly evaluation:
 - a. A cardiac catheterization was performed and not all coronary arteries were identified.
 2. Thoracic arteriovenous anomaly evaluation:
 - a. A cardiac MRI or chest CT angiogram was performed and suggested congenital heart disease.
 3. Complex congenital heart disease evaluation:
 - a. No cardiac CT or cardiac MRI has been performed (e.g., there is a contraindication to MRI) or cardiac CT or cardiac MRI was performed one or more years ago.
 - C. Cardiac CT angiography:
 1. Evaluation of known coronary artery disease (CAD) documented by prior imaging stress test, cardiac catheterization, cardiac CT angiogram, coronary revascularization, carotid stenosis or stroke, peripheral artery disease or aortic aneurysm:
 - a. New chest pain or shortness of breath with prior coronary artery bypass grafting and no exclusions to cardiac CT angiography; or

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- b. No new chest pain or shortness of breath and a left main stent of 3 mm or more is present and there are not exclusions to cardiac CT angiography.
- 2. Evaluation of known coronary artery disease (CAD) documented by a prior calcium scores less than 400:
 - a. Evaluation of new chest pain or dyspnea, no imaging stress test is planned, and there are no exclusions to cardiac CT angiography.
- 3. Evaluation of suspected coronary artery disease with new or changed chest pain or shortness of breath:
 - a. Urgent presentation of acute symptoms can proceed to cardiac CT angiography without stress testing of any type and regardless of pretest probability.
 - b. Contraindications to a routine exercise stress test (inability to exercise, diabetes, digoxin use, poor heart rate response, Wolff-Parkinson-White syndrome, complete LBBB, 1 mm or more ST-J depression with horizontal or downsloping ST segments 80 ms after the J point, or ventricular paced rhythm):
 - i. Low or intermediate risk on the pre-test probability assessment; AND
 - ii. No exclusions to cardiac CT angiography.
 - c. No contraindications to a routine exercise stress test:
 - i. Normal routine exercise stress with new or worsening chest pain or shortness of breath, cardiac catheterization is not planned and there are no exclusions to cardiac CT angiography; or
 - ii. Routine exercise stress test is abnormal or not performed and low or intermediate risk on the pre-test probability assessment and no exclusion to cardiac CT angiography.
- 4. Evaluation of suspected coronary artery disease and prior imaging stress test:
 - a. Normal stress test (e.g., SPECT, stress echocardiogram, exercise tolerance test [ETT]); and
 - i. New or worsening chest pain or shortness of breath; and
 - ii. Cardiac catheterization is not planned; and
 - iii. No exclusions to cardiac CT angiography.
 - b. Abnormal imaging stress test documenting any of the following if no exclusion to cardiac CT angiography are present:
 - i. Normal treadmill with reversible perfusion abnormality or wall motion abnormality including transient ischemic dilatation; or
 - ii. Equivocal; or
 - iii. Abnormal treadmill with normal imaging.
- 5. Evaluation of suspected coronary artery disease in patients prior to non-coronary cardiac surgery; and
 - a. Intermediate risk on the pre-test probability assessment and no exclusion to cardiac CT angiography.
- 6. Evaluation of suspected coronary artery disease with suspected anomalous coronary artery; and
 - a. Cardiac catheterization was performed, all coronary arteries were not identified, and no exclusion to cardiac CT angiography.
- 7. New onset of congestive heart failure without known coronary artery disease to assess coronary arteries; and
 - a. Low or intermediate risk on the pre-test probability assessment, the ejection fraction is less than 50% and no exclusion to cardiac CT angiography.

II. Based on our criteria and review of the peer reviewed literature, it is **medically appropriate** for patients who are candidates for CTA to have calcium scoring performed as part of a CTA procedure, since pre-test knowledge of extensive calcification of the coronary segment in question may diminish the interpretive value of a cardiac CTA.

III. Based upon our criteria and review of the peer-reviewed literature, cardiac computed tomographic angiography is considered **investigational** for all other indications.

POLICY GUIDELINES:

- I. The following are examples of contraindications to the use of cardiac CT angiography:
 - A. Atrial fibrillation;
 - B. Multifocal atrial tachycardia;
 - C. Inability to lie flat;
 - D. Body mass index of greater than 40;
 - E. Inability to obtain a heart rate of less than 65 beats per minute after beta blockers;

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- F. Calcium score of greater than 1000;
- G. Inability to breath hold for greater than 8 seconds;
- H. Renal insufficiency (creatinine greater than 1.8 mg/dl).

II. Per appropriateness criteria from a multidisciplinary cardiac CTA and cardiac MRI work group (Hendel, et al., 2006) chest pain syndrome is defined as 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:

- A. Chest pain;
- B. Chest tightness;
- C. Chest burning;
- D. Dyspnea;
- E. Shoulder pain; or
- F. Jaw pain.

III. Pre-test probability of coronary artery disease can be categorized as low, intermediate or high. It is based upon the character of chest pain symptoms as well as age and gender. The character of chest pain is classified as either typical (or classical) angina, atypical angina or nonanginal. If the symptoms of substernal chest pain which is precipitated by exertion and relieved within 10 minutes with rest or nitroglycerin is present, it is considered typical (or classical) angina. Atypical angina occurs when only two symptoms are present. When one or no symptoms are present, it is considered nonanginal chest pain. Once the nature of the chest pain is determined, the following classifications can be estimated:

- A. Low Probability (less than 10%):
 - 1. Asymptomatic men and women of all ages,
 - 2. Women less than 50 years with atypical chest pain.
- B. Intermediate Probability (10%-90%):
 - 1. Men of all ages with atypical angina,
 - 2. Women greater than 50 years with atypical angina,
 - 3. Women 30-50 years with typical angina.
- C. High Probability:
 - 1. Men greater than 40 years with typical angina,
 - 2. Women greater than 60 years with typical angina.

IV. Diabetic patients with chest pain are considered to be at intermediate to high risk pretest probability of coronary artery disease.

V. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

Refer to Corporate Medical Policy #6.01.13 regarding Computed Tomography (EBCT, Spiral CT, MDCT) for Detection of Coronary Artery Calcification (cardiac calcium scoring).

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

DESCRIPTION:

Computed tomographic angiography or CTA is a non-invasive 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. 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 the heart rate below 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.

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Rapid scanning is also helpful so that the volume of cardiac images can be obtained during breath-holding. Very thin sections (less than 1 mm) are important to provide adequate spatial resolution and high-quality 3D reconstruction images.

Two different CT technologies can achieve high-speed CT imaging. Electron beam CT (EBCT, ultrafast CT).

The radiation dose associated with contrast-enhanced cardiac CTA is an important consideration. 4-row MDCT with 1-mm sections delivers approximately 7.1 to 11.9 mSv (millisievert or one thousandth of a sievert); 16-row MDCT with 0.75-mm sections delivers approximately 8.8 mSv; EBCT using ECG triggering with 3-mm sections delivers approximately 0.7 to 1.1 mSv. While radiation dose exposure with conventional invasive coronary angiography depends on equipment and operator technique, it delivers approximately 4-8 mSv. It is proposed 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.

Cardiac CTA has been proposed as a noninvasive alternative to invasive coronary angiography. Applications include but are not limited to evaluation of obstructive coronary artery disease (CAD), coronary artery bypass graft patency, coronary artery stent patency, coronary artery aneurysm, delineation of coronary artery anomaly and functional cardiac assessment.

It is recognized that calcium scoring is an integral part of CTA to determine the risk-benefit of dye infusion.

RATIONALE:

Contrast-enhanced cardiac CT angiography can be performed using either multidetector-row CT (MDCT) or electron beam CT (EBCT). Multiple manufacturers have received FDA 510(k) clearance to market MDCT machines equipped with at least 16 detector rows and at least two models of EBCT machines have been cleared through FDA 510(k) clearance. Intravenous iodinated contrast agents used for cardiac CTA have also received FDA approval.

Prospective studies with small sample sizes conclude that cardiac CTA is a promising noninvasive method for assessment of coronary stents, detection of in-stent restenosis and occlusion, and for evaluating bypass patency. Studies with small sample sizes conclude that the presence of myocardial hypoenhancement on cardiac CTA in acute chest pain patients has a high positive predictive value and specificity but only moderate sensitivity for presence of acute or healed MI. Additional studies conclude that the presence and size of early perfusion defects and late enhancement on cardiac CTA is closely related to follow-up segment myocardial dysfunction and myocardial functional recovery. Available studies recommend further studies to evaluate the clinical value of these preliminary findings in larger patient populations.

Current studies consist of patient populations with a high pretest probability of CAD. Patients providing suboptimal images are often excluded from calculations of test accuracy. Future studies will need to examine these tests in larger, less selected populations representing the clinical settings in which they are actually expected to be used.

However, appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging has been published. It is a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, the American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. The working group acknowledges that clinical evidence is limited regarding the clinical application of cardiac CT angiography in patient care algorithms and that there is little expert consensus. Although the appropriateness criteria are not specific guidelines, it is hoped that they may serve as an initial guide for this rapidly-evolving technology. The working group rates cardiac computed tomography as an appropriate test and a reasonable approach for the indications listed as medically appropriate in this medical policy.

In 2008, a scientific statement, "Noninvasive Coronary Artery Imaging. Magnetic Resonance Angiography and Multidetector Computed Tomography Angiography," was published by the American Heart Association Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention, and the Councils on Clinical Cardiology and Cardiovascular Disease in the Young. The scientific statement recommends criteria for cardiac CTA similar to the above Appropriateness Criteria, and specifically recommends against screening asymptomatic individuals for coronary artery disease.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 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 Computerized 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)

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HCPCS: No specific code(s)

ICD9: Numerous

ICD10: Numerous

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KEY WORDS:

Cardiac CTA, Coronary artery CTA, calcium scoring.

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

After examining the medical evidence, the Centers for Medicare and Medicaid Services (CMS) determined no national coverage determination (NCD) is appropriate at this time (March 12, 2008). Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local contractors through a local coverage determination process or case-by-case adjudication.

There is currently a Local Coverage Determination (LCD) for Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA). Please refer to the following LCD website for Medicare members:
http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=25907&ContrId=181&ver=48&ContrVer=1&CntrctrSelected=181*1&Cntrctr=181&name=National+Government+Services%2c+Inc.+%2813202%2c+MAC++Part+B%29&s=41&DocType=All&bc=AggAAAAIAAAAAAA%3d%3d&