CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Computed Tomography Angiography (CTA)**

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Cardiovascular Magnetic Resonance (CMR)
Electron Beam Computed Tomography (EBCT) and Multidetector Computed Tomography (MDCT) for Coronary Artery Calcification
Magnetic Resonance Angiography (MRA)

Coverage Policy

CIGNA covers multidetector-row computed tomography angiography (CTA) as medically necessary as an adjunct to other testing for ANY of the following indications:

<u>Head/Neck</u>

- suspected or known vascular pathology (e.g., stroke, subarachnoid hemorrhage, aneurysm, dissection, atherosclerotic disease, arteriovenous malformation)
- screening for intracranial aneurysm for EITHER:
  - a heritable disorder known to be associated with vascular anomalies (e.g., autosomal dominant polycystic kidney disease, Ehlers-Danlos syndrome, fibromuscular dysplasia, or a known aortic coarctation)
  - family history of at least one first-degree relative with a history of intracranial aneurysm
- surveillance of intracranial aneurysm in an individual with EITHER of the following:
  - a known unruptured intracranial aneurysm
  - an intracranial aneurysm previously treated with endovascular coiling or neurosurgical clipping

<u>Chest/Thorax</u>

- suspected or known vascular pathology (e.g., aortic dissection or aneurysm, arteriovenous malformation, pulmonary artery hypertension, subclavian steal syndrome, superior vena cava syndrome, thoracic outlet syndrome)
- suspected or known pulmonary embolism

Abdomen

- suspected or known vascular pathology (e.g., abdominal aortic aneurysm or dissection, renovascular hypertension)

Extremities

- suspected or known peripheral arterial disease

Other

- suspected or known vascular anomalies associated with congenital conditions (e.g., Marfan syndrome, pulmonary sequestration, complete and incomplete vascular rings)
- pulmonary veins and left atrium prior to radiofrequency ablation for atrial fibrillation or supraventricular tachycardia

CIGNA covers 64-slice or greater multidetector-row computed tomography angiography (CTA) as medically necessary as an adjunct to other testing for ANY of the following indications:

- evaluation of chest pain in an individual with a very low, low, or intermediate pre-test probability of coronary artery disease[1] (CAD) when the individual cannot perform or has a contraindication to exercise and chemical stress testing (i.e. exercise treadmill stress test, stress echo, and nuclear stress test [i.e., myocardial perfusion imaging])
- exclusion of CAD in an individual with a low or very low pre-test probability of CAD when recent stress test results (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are uninterpretable, equivocal, or there is a suspicion that the results are falsely positive
- exclusion of CAD in an individual with an intermediate pre-test probability of CAD when recent stress test results (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are uninterpretable or equivocal, AND CTA will be performed in lieu of an angiography.
- exclusion of CAD in a symptomatic individual (e.g., acute chest pain in an emergency department setting), and the individual has an intermediate pre-test probability of CAD, and there are no changes noted on the ECG and serial enzymes are negative
- evaluation of suspected or known coronary artery anomalies associated with congenital conditions
- for morphologic evaluation of the coronary arteries in an individual with dilated cardiomyopathy or new onset heart failure, when ischemia is the suspected etiology and cardiac catheterization and/or nuclear stress test (i.e., myocardial perfusion imaging) have not been performed
- pre-operative assessment of coronary arteries in an individual undergoing repair of aortic dissection, aortic aneurysm repair or valvular surgery AND CTA will be performed in lieu of an angiography
- post-coronary artery bypass grafting (CABG) when BOTH of the following criteria are met:
    - repeat intervention is being considered
    - recent coronary angiography has been completed but additional information is needed before a treatment decision can be made

CIGNA does not cover multidetector-row computed tomography angiography (CTA) for any other indication, including but not limited to those listed below, because it is considered experimental, investigational or unproven:

- evaluation of chest pain in an intermediate or high pre-test probability of CAD individual when recent stress test result (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are either clearly positive or unequivocally negative
- screening for CAD in an asymptomatic individual

- post-revascularization procedure (e.g., percutaneous coronary intervention, coronary artery bypass grafting surgery), including evaluation of bypass grafts, coronary anatomy or evaluation for in-stent restenosis except when an individual is post-coronary artery bypass grafting (CABG), repeat intervention is being considered but additional information is required following completion of recent coronary angiography.

[1] See Appendix A for definition of Pre-test Probability of CAD

General Background

The American College of Radiology (ACR) defines computed tomography angiography (CTA) as "a CT examination that is primarily performed for assessment of the heart, arteries, or veins of the body. It requires at a minimum a thin section helical (spiral) CT acquisition coupled with a power injection of intravenous iodinated contrast medium. Three dimensional rendering and multiplanar reformations are important components of many CTA examinations" (ACR, 2006). Computed tomography angiography or venography (CTA/CTV) involves injecting contrast material into a small peripheral vein by using a small needle or catheter to visualize blood flow in arterial and venous vessels throughout the body. Images are generated by a computer synthesis of x-ray transmission data obtained in many different directions in a given plane. Compared to catheter angiography, which involves placing a sizable catheter and injecting contrast material into a large artery or vein, CTA/CTV is a noninvasive procedure.

Imaging of the vessels is not necessarily CTA. The key distinction between CTA and CT is CTA includes reconstruction post-processing and interpretation. CTA offers important advantages over conventional angiography, which depicts only the vascular lumen. With CTA, additional information is provided, including vessel wall thickness, relationship to adjacent structures, enhanced depiction of the venous anatomy, and parenchymal information of the target organ and other structures within the scan range and field of view (ACR, 2003).

U.S. Food and Drug Administration (FDA)
Multiple manufacturers have received FDA 510(k) clearance to market CT machines. Multislice CT technology has evolved rapidly over the past several years, beginning with 4-slice scanners that were first introduced in 1998. Since then, multi-slice scanners have been approved and available for diagnostic use, with the first 64-slice system receiving FDA approval in 2004.

Literature Review

Head and Neck
CTA/CTV is a useful modality when head and neck vascular visualization is needed. CTA may be performed for suspected or known stroke, subarachnoid hemorrhage, aneurysm, dissection, atherosclerotic disease, and arteriovenous malformation. CTA can also be used to examine the intracranial venous system (CT venography, CTV), such as suspected dural sinus thrombosis. Due to its high sensitivity, the majority of studies support the use of CTA as a substitute for catheter angiography. Studies demonstrate that CTA has a significant positive effect on patient clinical management, or possibly avoids a potentially harmful procedure, digital subtraction angiography, or provides important preoperative information (Bash, et al., 2005; Koelemay, et al., 2004; Schramm, et al., 2004; Chappell, et al., 2003; Kokkinis, et al., 2008; Chen, et al., 2008). The American Heart Association (AHA) supports the use of CTA for clinical scenarios in transient ischemic attack and stroke (Latchaw, et al., 2009; Easton, et al., 2009).

Screening for and Surveillance of Intracranial Aneurysms
Evidence in the peer-reviewed scientific literature supports screening for and surveillance of intracranial aneurysms with CTA/CTV for certain population subsets. Specifically, the literature supports screening for individuals with a rare heritable disorder known to be associated with vascular anomalies (e.g., autosomal dominant polycystic kidney disease, Ehlers-Danlos syndrome, fibromuscular dysplasia, a known aortic coarctation). Additionally the literature supports screening in individuals with at least one first-degree relative with a history of intracranial aneurysm. Study results vary, but generally, screening becomes even more critical if the individual has greater than one first-degree relative with a history of intracranial aneurysm (i.e., familial

intracranial aneurysm) and if that individual also has a personal history of hypertension, smoking, or takes oral contraceptives. Because the age at which familial aneurysms arise tends to cluster, screening should start at the beginning of the decade in which the index subarachnoid hemorrhage occurred in the family member. The literature supports surveillance of intracranial aneurysms with CTA or MRA in individuals with known unruptured intracranial aneurysm or previously treated intracranial aneurysms. The literature varies in recommended frequency of screening or surveillance (e.g., every five to ten years) but does recommend annually imaging for an individual previously treated with endovascular coiling (Broderick, et al., 2009; Woo, et al, 2009; Bor, et al., 2008; Brown, et al., 2008; Wermer, et al., 2008; Suarez, et al., 2006; Wermer, et al., 2005a; Wermer, et al., 2005b; Vega, et al., 2002; Johnston, et al., 2002; Magnetic Resonance Angiography in Relatives of Patients with Subarachnoid Hemorrhage Study Group [The], 1999).

American Heart Association (AHA): The AHA Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage (SAH) (Bederson, et al. 2009) states “Screening of certain high-risk populations for unruptured aneurysms is of uncertain value (Class IIb); advances in noninvasive imaging may be used for screening, but catheter angiography remains the gold standard when it is clinically imperative to know if an aneurysm exists.” See Appendix B for ACC/AHA Definitions of Classification.

Thoracic/Abdominal
CTA/CTV is also a useful modality for thoracic and abdominal vascular imaging. The American College of Cardiology (Hendel, et al., 2006) states that CTA is appropriate for evaluation of suspected aortic dissection or thoracic aortic aneurysm and for evaluation of suspected pulmonary embolism. CTA may aid in diagnosis and surgical planning, and may sometimes obviate the need for conventional or digital angiography (Gluecker, et al., 2008; Hendel, et al., 2006; Stein, et al., 2006; Hogg, et al., 2006; Fraioli, et al., 2006; Reinartz, et al., 2004; Radan, et al., 2004).

Peripheral Arterial Disease
CTA/CTV is indicated in peripheral arterial disease (PAD). CTA is an accurate and reliable noninvasive alternative to digital subtraction angiography in the assessment of aortoiliac and lower extremity arteries in patients with PAD, including work-up to evaluate a potential revascularization procedure (ICSI, 2010; Met, et al., 2009; Ouwendijk, et al., 2008; Kock, et al., 2005; Ouwendijk, et al., 2005; Willmann, et al., 2005; Adriaensen, et al., 2004).

American College of Cardiology/American Heart Association (ACC/AHA): The ACC/AHA Practice Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) (Hirsch, et al., 2006) include the following recommendations specific to CTA:

Lower Extremity PAD:

- CTA of the extremities may be considered to diagnose anatomic location and presence of significant stenosis in patients with lower extremity PAD (Class IIb)
- CTA of the extremities may be considered as a substitute for MRA for those patients with contraindications to MRA (Class IIb)
- Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation (Class IIa)

Renal Arterial Disease:

- Duplex ultrasonography, CTA (in individuals with normal renal function), and MRA are recommended as screening tests to establish the diagnosis of renal artery stenosis (Class I)
- When the clinical index of suspicion is high and the results of noninvasive tests are inconclusive, catheter angiography is recommended as a diagnostic test to establish the diagnosis of renal artery stenosis (Class I)

Mesenteric Arterial Disease:

- Duplex ultrasound, CTA, and gadolinium-enhanced MRA are useful initial tests for supporting the clinical diagnosis of chronic intestinal ischemia (Class I)

See Appendix B for ACC/AHA Definitions of Classification.

Congenital Vascular Abnormalities
The ACC (Hendel, et al., 2006) states that CTA is appropriate for evaluation of complex congenital heart disease, including anomalies of coronary circulation, great vessels, and cardiac chambers and valves. CTA is appropriate for imaging vascular abnormalities associated with congenital conditions such as Marfan syndrome, pulmonary sequestration, and vascular rings (Bluemke, et al., 2008; Ha, et al., 2007; Goldstein, et al., 2007; Budoff, et al., 2006; Hendel, et al., 2006; Juraszek, et al., 2006; Berbarie et al 2006).

American College of Cardiology/American Heart Association (ACC/AHA): The ACC/AHA 2008 Guidelines for the Management of Adults With Congenital Heart Disease (Warnes, et al., 2008) included these recommendation specific to CTA:

- Recommendations for Evaluation of Patients With Supravalvular, Branch, and Peripheral Pulmonary Stenosis: Patients with suspected supravalvular, branch, or peripheral pulmonary stenosis should have baseline imaging with echocardiography-Doppler plus one of the following: MR angiography, CT angiography, or contrast angiography (Class I)
- Recommendations for Coronary Arteriovenous Fistula: If a continuous murmur is present, its origin should be defined either by echocardiography, MRI, CT angiography, or cardiac catheterization (Class I)

See Appendix B for ACC/AHA Definitions of Classification.

Prior to Radiofrequency Ablation
CTA may be indicated to evaluate pulmonary veins and left atrium prior to radiofrequency ablation for atrial fibrillation or supraventricular tachycardia to help identify multidimensional anatomical landmarks.

64-slice Or Greater Coronary CTA
Note: See Appendix A for definition of pre-test probability of coronary artery disease (CAD).
The American Heart Association states that 64-slice MDCT is the current standard for coronary CT angiography and noncalcified plaque characterization based on publications to date (Budoff, et al., 2006).

Studies in the peer-reviewed scientific literature support the use of at least 64-slice for coronary artery CTA (Hausleiter, et al., 2007; Sun, et al., 2006). Studies have demonstrated that 64-slice CTA performs with high accuracy for the diagnosis of CAD and can reduce referrals for invasive coronary angiography (Budoff et al., 2008a; Miller, et al., 2008; Budoff, et al., 2008b; Mowatt, et al., 2008a; Husmann, et al., 2008; Meijboom, et al., 2007). In a meta-analysis on the diagnostic accuracy of 64-channel coronary CTA, six studies were found involving a total of approximately 350 coronary artery bypass graft (CABG) patients. Coronary CTA was able to detect complete occlusion of grafts with a sensitivity of 97% and a specificity of 100% (calculated on a per-graft rather than a per-patient basis). Considering both significant stenosis and occlusion, sensitivity was 98% and specificity was 97%. Likelihood ratios indicate that coronary CTA can rule in or rule out graft disease with a high degree of certainty in patients with an intermediate pretest probability of disease (Stein, et al., 2008; ACC, 2010).

The accuracy of 64-slice CTA in patients who have undergone stent placement has yet to be proven. Carrabba et al. (2010) conducted a meta-analysis to evaluate the diagnostic accuracy of 64-slice CTA compared with invasive coronary angiography for in-stent re-stenosis (ISR) detection. A total of 598 patients with 978 stents were included. Although CTA had a good diagnostic accuracy for ISR detection, there is still a relatively large proportion of stents that remain uninterpretable. Due to image quality, there is a large percentage of non-assessable CTA's. Though it appears the larger the stent, the greater chance of obtaining assessable, accurate CTA readings, variations in diagnostic performance among different individual stents and population subtypes will require validation in larger studies (ACC, 2010).

Initial studies support the clinical utility of CTA. Hoffmann et al. (2009) performed urgent CTA in 368 symptomatic individuals with low and intermediate pre-test probability of CAD and normal ECG. There were eight (2.1%) patients who proved to have an acute MI, and a further 23 (6.3%) had a final diagnosis of acute coronary syndrome. The remaining 337 patients (91.6%) had no evidence of active myocardial ischemia at the time of hospital discharge. Over a mean follow-up of 6.2 months, none of these 337 patients had a major cardiac event. The authors noted that early coronary CTA in the emergency department may significantly improve patient management by aiding clinical decision making, specifically early discharge of subjects at low to intermediate likelihood of acute coronary syndrome without CAD. In a prospective longitudinal study, 2,076 patients were followed for a mean of 16± 8 months. Using CTA, CAD severity was a predictor of major adverse cardiac events (MACE) and left ventricular ejection fraction (LVEF) had incremental value over CAD severity. Total plaque score had incremental value over CAD severity and LVEF for all cause mortality and nonfatal myocardial infarction. These values obtained with CTA, have prognostic and incremental value over routine clinical predictors (the National Cholesterol Education Program/Adult Treatment Panel III Guidelines) (Chow, et al., 2010).

Technology Assessments: The Health Technology Assessment (HTA) Program, part of the United Kingdom (UK) National Institute for Health Research (NIHR), published a Health Technology Assessment (Mowatt, et al., 2008b). Mowatt et al. conducted a systematic review and evaluated the clinical effectiveness, in different patient groups, of the use of 64-slice or higher CTA, instead of invasive angiography, for diagnosing people with suspected CAD and assessing people with known CAD. The diagnostic accuracy and prognostic studies enrolled over 2500 and 1700 people, respectively. Mowatt et al. reports that the technical factors that enhance image quality in 64-slice CT also result in a higher radiation dose, although the use of electrocardiogram (ECG)-dependent dose modulation can reduce this by 30–50%. The proportion of invasive angiography that could be replaced by 64-slice CT is currently uncertain. Reduction in invasive angiography would be mainly at the diagnostic end of the pathway, in both elective assessment of chest pain of possibly anginal origin, and assessment of suspected acute coronary syndromes in some patients with normal or equivocal ECGs and negative troponin tests. In the emergency situation, some hospital admissions might be avoided. However, to do so, 64-slice CT would need to be readily available, ideally on a 24-hour basis, which is unlikely to be the case in most hospitals. Mowatt et al. also notes that some perfusion studies could also be replaced by 64 slice CT angiography. In summary, the main value of 64-slice CT may at present be to rule out significant CAD. It is unlikely to replace CA in assessment for revascularization of patients, particularly as angiography and angioplasty are often done on the same occasion.

The California Technology Assessment Forum (CTAF) published CTA in the Diagnosis of Coronary Artery Stenosis and for the Evaluation of Acute Chest Pain (October 2007). The CTAF notes that cardiac CTA is being evaluated for use in the diagnosis of coronary artery stenosis or for the evaluation of acute chest pain. Although several studies have assessed diagnostic accuracy of CTA (e.g., sensitivity and specificity), fewer have assessed clinical outcomes or compared CTA to conventional diagnostic strategies. Additional limitations include the inability of CTA to accurately assess all the coronary arteries (a certain percentage of the arteries are read as indeterminate which then leads to additional diagnostic testing), and the risks of radiation exposure and nephrotoxicity. CTAF states:

- CTA as a substitute for coronary angiography for the diagnosis of coronary artery stenosis does not meet the CTAF criteria for safety, efficacy and improvement in health outcomes.
- CTA in the evaluation of acute chest pain in the ER does not meet CTAF criteria for safety, efficacy and improvement in health outcomes.

The Health Technology Assessment (HTA) Program published a Health Technology Assessment (Collins, et al., 2007). Collins et al. conducted a systematic review of duplex ultrasound, MRA and CTA for the diagnosis and assessment of symptomatic, lower limb PAD. Collins et al. concluded that contrast enhanced (CE) MRA has the best overall diagnostic accuracy of the three index tests evaluated. Where available, CE MRA may be a viable alternative to contrast angiography. The overall diagnostic performance of CTA in detecting stenoses of 50% or more was inferior to CE MRA. However, the results for the performance of CTA to image arteries of the foot appear promising. As the assessment of PAD is a relatively new application for this technology, there was insufficient evidence to evaluate the usefulness of CTA in this area.

The Medicare Coverage Advisory Commission published a technology assessment on noninvasive imaging for CAD (Patel, et al., 2007). A review of the available scientific evidence through 2005 was conducted for direct noninvasive imaging tests for CAD. Specifically, a search for 16 (and higher) CTA and 1.5 Tesla MRA to evaluate for stenosis in native coronary arteries, resulted in 123 articles. The authors concluded that “the evidence base for noninvasive direct coronary imaging technologies is currently inadequate for routine use in the diagnosis and management of CAD. Although the sensitivity and specificity of noninvasive direct coronary imaging technologies on a per patient basis look promising, specifically with 64-slice CTA, current studies are limited by number of studies available to determine if the data are generalizable to the U.S. Medicare population. Evaluation of noninvasive technologies in appropriate clinical situations, in patients with well-defined risk, at multiple centers is required. In addition, studies evaluating these technologies and their resultant effects on both clinical management and patient outcomes are lacking and needed. The ability to noninvasively image the coronary arteries provides the potential to leap into an age of improved early diagnosis and therapy for CAD.

The burden of proof lies on the cardiovascular community to ensure that patients, payers, and clinicians realize this potential."

The Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Technology Assessment 'Contrast-Enhanced Cardiac Computed Tomographic Angiography in the Diagnosis of Coronary Artery Stenosis or for Evaluation of Acute Chest Pain' (August, 2006) concluded that the available evidence is inadequate to determine whether CTA improves the net health outcome or is as beneficial as established alternatives for diagnosis of coronary artery stenosis or for evaluation of acute chest pain in the ER. CTA as a substitute for coronary angiography in the diagnosis of coronary artery stenosis does not meet criteria. CTA in the evaluation of acute chest pain in the emergency room also does not meet criteria.

Professional Societies/Organizations (Coronary CTA)

American College of Cardiology (ACC)
The ACC, American College of Radiology (ACR), 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 published Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging in October 2006 (Hendel, et al., 2006). Some include:

- For the detection of CAD in symptomatic patients, evaluation of chest pain syndrome, CTA is: Appropriate, if intermediate pre-test probability of CAD and ECG uninterpretable or unable to exercise
- For the detection of CAD in symptomatic patients, evaluation of intracardiac structures, CTA is: Appropriate, if evaluation of suspected coronary anomalies
- For the detection of CAD in symptomatic patients, acute chest pain, CTA is: Appropriate, if intermediate pre-test probability of CAD and no ECG changes and serial enzymes negative
- For Detection of CAD with Prior Test Results, Evaluation of Chest Pain Syndrome, CTA is: Appropriate, if uninterpretable or equivocal stress test (exercise, perfusion, or stress echo)

- For Morphology, CTA is:
  - Appropriate, if assessment of complex congenital heart disease, including anomalies of coronary circulation, great vessels, and cardiac chambers and valves
  - Appropriate, if evaluation of coronary arteries in patients with new onset heart failure to assess etiology

- For Evaluation of Aortic and Pulmonary Disease, CTA is:
  - Appropriate, if evaluation of suspected aortic dissection or thoracic aortic aneurysm
  - Appropriate, if evaluation of suspected pulmonary embolism

- For the detection of CAD, post-revascularization (PCI or CABG), evaluation of chest pain syndrome, CTA is:
  - Uncertain, if evaluation of bypass grafts and coronary anatomy
  - Uncertain, if history of percutaneous revascularization with stents
- For the detection of CAD, post-revascularization (PCI or CABG), asymptomatic, CTA is
  - Inappropriate, if evaluation of bypass grafts and coronary anatomy and less than five years after CABG
  - Inappropriate, if evaluation of bypass grafts and coronary anatomy and greater than or equal to five years after CABG
  - Inappropriate, if evaluation for in-stent restenosis and coronary anatomy after PCI

Note: See Appendix A for definition of pre-test probability of CAD.

The ACC/ACR 2010 expert consensus document on coronary computed tomographic angiography states that currently, cardiac CTA can provide information about coronary anatomy and left ventricular (LV) function that can be used in the evaluation of patients with suspected or known CAD. In the future, the ability of CTA to provide information not currently available from invasive angiography may provide the basis for a major shift in how patients with atherosclerotic cardiovascular disease are classified and managed (ACC, 2010).

American Heart Association (AHA)
The AHA published a Scientific Statement "Noninvasive Coronary Artery Imaging: Magnetic Resonance Angiography and Multidetector Computed Tomography Angiography" (Bluemke, et al., 2008). The AHA states

that the chief advantages of coronary CTA compared with MRA are wider availability, higher spatial resolution, and more consistent, shorter examinations with better patient adherence. Advantages associated with coronary MRA are a lack of ionizing radiation and a lack of administration of iodinated contrast material. Both tests are presently suboptimal for patients with atrial fibrillation and other arrhythmias, and image quality may be further reduced by high body mass. The AHA notes that specific recommendations for use of these technologies are expected to change along with advances in scanner hardware and software. At present, the following general statements represent the consensus opinions of the writing group:

1. Neither coronary CTA nor MRA should be used to screen for CAD in patients who have no signs or symptoms suggestive of CAD. (Class III)

2. No multivendor trial data are available for coronary MDCT CTA or for present whole-heart coronary MRA. Thus, the applicability of these methods beyond the reporting research centers is unknown. Ideally, both multivendor and additional multicenter validation of these methods should be performed. (Class I)

3. The potential benefit of noninvasive coronary angiography is likely to be greatest and is reasonable for symptomatic patients who are at intermediate risk for CAD after initial risk stratification, including patients with equivocal stress-test results. (Class IIa)
Diagnostic accuracy favors coronary CTA over MRA for these patients. (Class I)
Concerns regarding radiation dose limit the use of coronary CTA in high-risk patients who have a very low pre-test likelihood of coronary stenoses; patients with a high pre-test likelihood of coronary stenoses are likely to require intervention and invasive catheter angiography for definitive evaluation; thus, CTA is not recommended for those individuals. (Class III)
Pronounced coronary calcification may negatively impact interpretability and accuracy of coronary CTA and thus, the usefulness of CTA is uncertain in these individuals. (Class IIb)

4. Anomalous coronary artery evaluation can be performed by either CTA or MRA; radiation-protection concerns indicate that MRA is preferred when it is available. (Class IIa)

5. Reporting of coronary CTA and MRA results should describe any limitations to the technical quality of the examination and the size of the vessels, descriptions of coronary anomalies, coronary stenosis, and significant noncardiac findings within the field of view. (Class I)

6. Continued research in cardiac CT and MR imaging is encouraged to determine the potential of these noncatheter- based modalities to detect, characterize, and measure atherosclerotic plaque burden, as well as its change over time or as the result of therapy. (Class I).
See Appendix B for ACC/AHA Definitions of Classification.

The AHA published a scientific statement on assessment of CAD by cardiac computed tomography in October 2006 (Budoff, et al., 2006). Recommendations specific to CTA include:

- Suspected CAD: CT coronary angiography is reasonable for the assessment of obstructive disease in symptomatic patients (Class IIa). Use of CT angiography in asymptomatic persons as a screening test for atherosclerosis (noncalcific plaque) is not recommended (Class III)
- Follow-Up of Percutaneous Coronary Intervention: Imaging of patients to follow-up stent placement cannot be recommended (Class III).
- Follow-Up After Bypass Surgery: In most studies, the accuracy to detect bypass occlusion approached 100%. Clinically, however, it might be reasonable in most cases to not only assess the patency of the bypass graft but also the presence of coronary stenoses in the course of the bypass graft or at the anastomotic site, as well as in the native coronary artery system (Class IIb). This is more difficult, owing to the smaller caliber of these vessels, the presence of artifacts caused by metal clips, and the often pronounced coronary calcification.
- Anomalous Coronary Arteries: It reasonable to use CTA as one of the first-choice imaging modalities in the workup of known and suspected coronary anomalies (Class IIa).
  See Appendix B for ACC/AHA Definitions of Classification.

European Society of Cardiology
A Writing Group deployed by the Working Group Nuclear Cardiology and Cardiac CT of the European Society of Cardiology and the European Council of Nuclear Cardiology published a report on Cardiac Computed Tomography (Schroeder, et al., 2008). The following recommendations addressed CTA:

Detection of Coronary Artery Stenoses: the clinical application of coronary CTA to detect or rule out coronary artery stenoses seems most beneficial and, according to current data, can be recommended in patients with intermediate risk of CAD in whom the clinical presentation— stable or with acute symptoms—mandates the evaluation of possible underlying CAD. A similar conclusion was reached in an expert consensus document on 'appropriate' indications for cardiac CT and cardiac magnetic resonance imaging (Hendel, et al., 2006).The use of coronary CTA should be restricted to patients in whom diagnostic image quality can be expected (e.g., absence of arrhythmias), and scans need to be expertly performed and interpreted.

Coronary Stent Imaging: Although in single, carefully selected cases (e.g., large diameter stents in a proximal vessel segment, low and stable heart rate, and absence of excessive image noise) coronary CTA may be a possibility to rule out in-stent restenosis, routine application of CT to assess patients with coronary stents can currently not be recommended. Visualization of the stent lumen is often affected by artifacts, and especially the positive predictive value is low.

Coronary Artery Bypass Grafts: Although the clinical application of CTA may be useful in very selected patients in whom only bypass graft assessment is necessary (e.g., failed visualization of a graft in invasive angiography), the inability to reliably visualize the native coronary arteries in patients post-CABG poses severe restrictions to the general use of CTA in post-bypass patients.

Coronary Artery Anomalies: The robust visualization and classification of anomalous coronary arteries make CTA a first-choice imaging modality for the investigation of known or suspected coronary artery anomalies. Radiation dose must be considered often in the young patients, and measures to keep dose as low as possible must be employed.

Non-calcified Plaque: The fact that there is currently a lack of prospective clinical data that would support the use of contrast-enhanced CTA for the assessment of non-stenotic plaque does not allow clinical applications in asymptomatic individuals for the purpose of risk stratification. However, the tremendous potential of CTA for visualization and characterization of coronary plaques must be recognized and further research is strongly supported.

Left and Right Ventricular Function: Although CT imaging allows accurate assessment of left and right ventricular function, CT examinations will in most cases not be performed specifically for that purpose. Other diagnostic tests without radiation exposure or the need for contrast injection (i.e. echocardiography) are the methods of choice. However, it should be noted that ventricular function is adjunct information that can be obtained from standard coronary CTA investigations without altering the image acquisition protocol, and the ability of CT to provide accurate right ventricular assessment might be useful in several clinical conditions including congenital heart disease, carcinoid heart disease, or prior to lung transplantation.

North American Society of Cardiac Imaging and the European Society of Cardiac Radiology
The NASCI/ESCR published a consensus/position statement on the use of multidetector computed tomography for the assessment of acute chest pain. Stillman et al. (2007) states, "specific emergency department chest-pain protocols in which the differential diagnosis includes a coronary artery etiology can be divided into two groups. If the patient is stable and primary clinical suspicion is angina, a dedicated cardiac CTA may be sufficient. Alternatively, if the clinical evaluation is less specific and differential considerations include angina and other serious causes of acute chest pain, a comprehensive or global evaluation may be deemed appropriate. The latter protocol is also termed the triple threat or triple rule-out protocol."

American College of Radiology (ACR)
The ACR Practice Guideline for the Performance and Interpretation of CTA (2006) states that CTA "is a proven and useful procedure for the detection and characterization of vascular diseases and of vascular anatomy relevant to the treatment of extravascular disorders. CTA may be used as the primary modality for detecting disease or as an adjunctive tool for better characterizing known disease or assessing changes in disease state over time." It notes that CTA "is primarily performed for assessment of the heart, arteries, or veins of the body."

The Practice Guideline states that indications for CTA of cardiac and extracardiac vessels include, but are not limited to, the diagnosis, characterization, and/or surveillance of:

- arterial and venous aneurysms
- atherosclerotic occlusive disease
- nonatherosclerotic, noninflammatory vasculopathy
- traumatic injuries to arteries and veins
- arterial dissection and intramural hematoma
- arterial and venous thromboembolism
- congenital vascular anomalies
- vascular anatomic variants
- vascular interventions (percutaneous and surgical)
- vasculitis and collagen vascular diseases
- vascular infection

Radiation Exposure

The two safety issues involved in use of coronary CTA are related to the dose of radiation delivered during imaging and the need to use iodinated contrast material. The typical doses of radiation reported to be associated with coronary CTA exceed those reported for invasive coronary angiography. Radiation exposure and dose are inversely related to image noise and, by implication, image quality. Efforts at decreasing radiation exposure and patient dose should aim to deliver an image quality that allows confident image interpretation. Safe and effective use of contrast media is an important part of the clinical use of coronary CTA. Aside from allergic reactions, contrast medium-induced nephropathy is the major safety issue related to contrast administration. Measures to minimize the occurrence of contrast-induced nephropathy include screening patients by noting baseline serum creatinine levels and calculating glomerular filtration rates, noting any history and underlying conditions that would make the patient high risk, avoiding preprocedural dehydration, limiting contrast agent dose as much as possible, and ensuring adequate hydration before and after contrast exposure (ACC, 2010).

Summary

There is sufficient evidence in the peer-reviewed scientific literature supporting the use of noninvasive multidetector-row computed tomography angiography (CTA) and venography (CTV) as a vascular imaging technique that can be performed rapidly and safely for the assessment of many vascular diseases. Studies have demonstrated the high degree of accuracy of CTA compared to invasive angiography for imaging of vessels of the head, neck, thorax, abdomen and extremities. CTA can aid in evaluation of suspected pulmonary embolism and imaging vascular abnormalities associated with congenital conditions. CTA is useful in some population subsets for screening and surveillance of intracranial aneurysms.

There is sufficient evidence in the peer-reviewed scientific literature to support the use of 64-slice CTA as an adjunct to other testing in specific cardiac population subsets with low and intermediate pre-test probability of CAD. The literature regarding CTA performed on a multidetector-row scanner with less than 64 slices is not consistent, as is 64-slice literature in demonstrating high accuracy for the detailed diagnosis of CAD. Current literature does not provide sufficient evidence to support a role for CTA for asymptomatic population coronary artery disease (CAD) screening. Although less invasive than catheter-based coronary angiography, CTA still involves significant radiation exposure and the potential for iodinated contrast-related reactions. Practitioners of CTA should understand the potential risks of ionizing radiation exposure from the test and balance these risks against the potential benefits.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description

70496	CTA HEAD, with contrast material(s), including noncontrast images, if performed and image post-processing.
70498	CTA NECK, with contrast material(s), including noncontrast images, if performed and image post-processing.
71275	CTA CHEST, (non-coronary), with contrast material(s), including noncontrast images, if performed and image post-processing.
72191	CTA PELVIS, with contrast material(s), including noncontrast images, if performed and image post-processing.
73206	CTA Upper Extremity, with contrast material(s), including noncontrast images, if performed and image post-processing.
73706	CTA Lower Extremity, with contrast material(s), including noncontrast images, if performed and image post-processing.
74175	CTA ABDOMEN, with contrast material(s), including noncontrast images, if performed and image post-processing.
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)
75635	CTA ABDOMINAL AORTA and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed and image post-processing.
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 12/31/2009)
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 12/31/2009)
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 12/31/2009)
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 12/31/2009)

ICD-9-CM Diagnosis Codes	**Description**
411.1[†]	Intermediate coronary syndrome
413.0-413.9[†]	Angina Pectoris
414.01[†]	Coronary atherosclerosis of native coronary artery
414.9[†]	Unspecified chronic ischemic heart disease
415.11-415.19	Pulmonary embolism
428.0[†]	Congestive heart failure, unspecified
428.1[†]	Left heart failure
428.9[†]	Unspecified heart failure
429.2[†]	Unspecified cardiovascular disease

430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432.0-432.9	Other intracranial hemorrhage
433.00 – 433.91	Occlusion and stenosis of precerebral arteries
434.00 – 434.91	Occlusion of cerebral arteries
435.0 – 435.9	Transient cerebral ischemia
436	Acute but ill-defined cerebrovascular disease
437.0 – 437.9	Other and ill-defined cerebrovascular disease
440.0 – 440.9	Atherosclerosis
441.0 – 441.9	Aortic aneurysm and dissection
442.0 – 442.9	Other aneurysm
443.0 – 443.9	Other peripheral vascular disease
444.0 – 444.9	Arterial embolism and arthrosis
746.0-746.9	Other congenital anomalies of the heart
747.0 – 747.9	Other congenital anomalies of the circulatory system
786.50[†]	Unspecified chest pain

[†] **Note**: These indications are covered only if performed using 64-slice CT

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	**Description**
V45.81	Postprocedural aortocoronary bypass status
V81.0	Screening for ischemic heart disease

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APPENDIX A

From the American College of Cardiology (Hendel, et al., 2009):

Pre-Test Probability of CAD by Age, Gender, and Symptoms*

Age (Yrs)	Gender	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Nonanginal Chest Pain	Asymptomatic
<39	M F	Intermediate Intermediate	Intermediate Very low	Low Very low	Very low Very low
40-49	M F	High Intermediate	Intermediate Low	Intermediate Very low	Low Very low
50-59	M F	High Intermediate	Intermediate Intermediate	Intermediate Low	Low Very low
>60	M F	High High	Intermediate Intermediate	Intermediate Intermediate	Low 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.
*Modified from the ACC/AHA Exercise Testing Guidelines to reflect all age ranges (Gibbons, et al., 2002).

APPENDIX B

American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification used:

Class I: Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	9/15/2008	0399	Computed Tomography Angiography (CTA)
Great-West Healthcare	11/27/2007	05.330.03	Computed Tomography Angiography (CTA) of Coronary Arteries, Contrast-Enhanced