Contrast-enhanced computed tomography angiography (CTA) is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed computed tomography (CT) machinery to obtain detailed volumetric images of blood vessels. It is a potential alternative to current diagnostic tests for cardiac ischemia, i.e., non-invasive stress testing and/or coronary angiography.

Contrast-enhanced computed tomography angiography (CTA) can be applied to image blood vessels throughout the body; however, for 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 the heart rate below approximately 60–65 beats per minute to facilitate adequate scanning, and electrocardiographic triggering or gating (retrospective or prospective) 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 or less) are important to provide adequate spatial resolution and high-quality 3D reconstruction images.

Volumetric imaging permits multiplanar reconstruction of cross-sectional images to display the coronary arteries. Curved multiplanar reconstruction and thin-slab maximum intensity projections provide an overview of the coronary arteries, and volume-rendering techniques provide a 3D anatomical display of the exterior of the heart. 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 as 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 scanning, is a technologic 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. MDCT machines currently in use have 64 or more detectors.

A variety of noninvasive tests are used in the diagnosis of coronary artery disease (CAD). They can be broadly classified as those that detect functional or hemodynamic consequences of obstruction and ischemia (exercise treadmill testing, myocardial perfusion imaging [MPI], stress echo with or without contrast), and others that identify the anatomic obstruction itself (coronary CTA and coronary magnetic resonance imaging [MRI]). (1) Functional testing involves inducing ischemia by exercise or pharmacologic stress and detecting its consequences. However, not all patients are candidates. For example, obesity or obstructive lung disease can make obtaining echocardiographic images of sufficient quality difficult. Conversely, the presence of coronary calcifications can impede detecting coronary anatomy with coronary CTA. Accordingly, some tests will be unsuitable for particular patients.

Evaluation of obstructive CAD involves quantifying arterial stenoses to determine whether significant narrowing is present. Lesions with greater than 50% to 70% diameter stenosis accompanied by symptoms are generally considered significant and often result in revascularization procedures. It has been suggested that coronary CTA may be helpful to rule out the presence of CAD and to avoid invasive coronary angiography (ICA) in patients with a low clinical likelihood of significant CAD. Also of note is the interest in the potential important role of non-obstructive plaques (i.e., those associated with <50% stenosis) because their presence is associated with increased cardiac event rates. (2) Coronary CTA can also visualize the presence and composition of these plaques and quantify the plaque burden better than conventional angiography, which only visualizes the vascular lumen. Plaque presence has been shown to have prognostic importance.

The information sought from angiography after coronary artery bypass graft (CABG) 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. Symptomatic manifestations may include ischemia or syncope. Clinical presentation of anomalous coronary arteries is difficult to distinguish from other more common causes of cardiac disease; however, an 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 anomaly.

Coronary 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.
Radiation delivered with current generation scanners utilizing reduction techniques (prospective gating and spiral acquisition) has declined substantially—typically to under 10 mSv. For example, an international registry developed to monitor coronary CTA radiation recently reported a median 2.4 mSv (interquartile range, [IQR]: 1.3 to 5.5) exposure. (3) In comparison, radiation exposure accompanying rest-stress perfusion imaging ranges varies according to isotope used—approximately 5 mSv for rubidium-82 (PET), 9 mSv for sestamibi (SPECT), 14 mSv for F-18 FDG (PET), and 41 mSv for thallium; during diagnostic invasive coronary angiography, approximately 7 mSv will be delivered. (4) EBCT using electrocardiogram (ECG) triggering delivers the lowest dose (approximately 0.7 to 1.1 mSv with 3-mm sections). Any cancer risk due to radiation exposure from a single cardiac imaging test depends on age (higher with younger age at exposure) and gender (greater for women). (5-7) Empirical data (8) suggest that every 10 mSv of exposure is associated with a 3% increase in cancer incidence over 5 years.

The use of electron beam CT or helical CT to detect coronary artery calcification is addressed in a separate policy (No. 6.01.03).

Policy
Contrast-enhanced computed tomographic angiography for evaluation of anomalous (native) coronary arteries in symptomatic patients may be considered medically necessary when conventional angiography is unsuccessful or equivocal and when the results will impact treatment.

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 is considered medically necessary.

Contrast-enhanced computed tomographic angiography for coronary artery evaluation is considered investigational for all other indications.

Policy Guidelines
Effective in 2010, there are category I CPT codes for these services:

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)
Between 2006 and 2010, there was a series of category III CPT codes for CTA:

0146T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image post processing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium

0147T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image post processing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

0148T 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 and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium

0149T 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 and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

Rationale
This policy was originally based on a literature search conducted on MEDLINE® via PubMed through February 2004 and updated with subsequent literature review and/or repeat TEC Assessments. (9-11) The most recent literature review covers the period from August 2011 through September 2012.

The objective of the 2005 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 (ICA), particularly in patients with a low probability of significant coronary artery stenosis. Evaluation of the coronary artery anatomy and morphology was the most frequent use of cardiac CTA and primary focus of the TEC Assessment. The Assessment considered multiple indications, but computed tomography (CT) technology used in studies reviewed is now outdated (studies employed 16-slice scanners). 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 2006 TEC Assessment was undertaken to determine the usefulness of CTA as a substitute for ICA for 2 indications: in the diagnosis of coronary artery stenosis and in the evaluation of acute chest pain in the emergency department. Just 7 studies performed in the ambulatory setting utilizing 40 to 64 slice scanners were identified. Two studies performed in the emergency department used 4- or 16-slice scanners. Evidence was judged insufficient to form conclusions. Available studies at the time were inadequate to determine the effect of CTA on health outcomes for the diagnosis of coronary artery stenosis in patients referred for angiography or for evaluation of acute chest pain in the emergency department.
Three indications for cardiac or coronary CTA are considered in the current policy: 1) evaluation of anomalous coronary arteries, 2) patients with acute chest pain without known coronary disease presenting in the emergency department (ER) setting, and 3) evaluation of stable patients with signs and symptoms of CAD in the non-ER setting.

**Anomalous Coronary Arteries**

Anomalous coronary arteries are an uncommon finding during angiography, occurring in approximately 1% of coronary angiograms completed for evaluation of chest pain. However, these congenital anomalies can be clinically important depending on the course of the anomalous arteries. A number of case series have consistently reported that coronary CTA is able to delineate the course of these anomalous arteries, even when conventional angiography cannot. (12-15) However, none of the studies reported results when the initial reason for the study was to identify these anomalies, nor did any of the studies discuss impact on therapeutic decisions. Given the uncommon occurrence of these symptomatic anomalies, it is unlikely that a prospective trial of coronary CTA could be completed. Thus, a policy statement includes this application (i.e., evaluating anomalies in native coronary arteries) as medically necessary in symptomatic patients only when conventional angiography is non-diagnostic and when the result will have an impact on treatment.

**Patients with Acute Chest Pain Presenting to the Emergency Setting**

A 2011 TEC Assessment examined evidence surrounding the evaluation of patients with acute chest pain and without known coronary artery disease (CAD). (11) Randomized controlled trials (RCTs) and prospective observational studies reporting prognosis were identified by searching the MEDLINE database and relevant bibliographies of key studies.

Several RCTs of CTA conducted in emergency settings were identified. An RCT of Goldstein et al. evaluated 197 randomized patients from a single center without evidence of acute coronary syndromes to coronary CTA (n=99) or usual care (n=98). (16) 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. A second trial (CT-STAT) evaluated a similar sample of 699 randomized patients from 16 centers—361 undergoing coronary CTA and 338 myocardial perfusion imaging (MPI). (17) 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 (7.2% after coronary CTA; 6.5% after perfusion imaging). 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 department costs lower with coronary CTA.

An RCT by Litt et al. also evaluated the safety of coronary CT in the evaluation of patients in the emergency department. (18) Although the study was a randomized comparison to traditional care, the principal outcome was the safety outcomes of subjects with negative CTA examinations. No patients who had negative CTA examinations (n=460) died or had a myocardial infarction within 30 days. Compared with traditional care, patients in the CTA group had higher rates of discharge from the emergency department (49.6% vs. 22.7%), a shorter length of stay (median 18.0 hours vs. 24.8 hours), and a higher rate of detection of coronary disease (9.0% vs. 3.5%). Another RCT by Hoffmann et al. compared length of stay and patient
outcomes in patients evaluated with CTA versus usual care. (19) In patients in the CTA arm of the trial, the mean length of stay in the hospital was reduced by 7.6 hours, and more patients were discharged directly from the emergency department (47% vs. 12%). There were no undetected coronary syndromes and no differences in adverse events at 28 days. However, in the CTA arm, there was more subsequent diagnostic testing and higher cumulative radiation exposure. The cumulative costs of care were similar between the two groups.

Two studies reported no cardiac events following a negative coronary CTA in the emergency department after 12 months’ (n=481) (20) and 24 months’ (n=368) (21) follow-up.

Conclusions. An overall assessment of the studies would appear to provide the following conclusions. Owing to the high negative predictive value of coronary CTA in this population of patients presenting to the ED with chest pain, the test offers an alternative for patients and providers. Evidence obtained in the emergency setting, similar to more extensive results among ambulatory patients, indicates a normal coronary CTA provides a prognosis at least as good as other negative non-invasive tests. The efficiency of the workup is improved, as patients are more quickly discharged from the emergency department with no adverse outcomes among patients who have negative CTA examinations.

Other important outcomes that require consideration in comparing technologies include invasive coronary angiography rates, use of a second non-invasive test, radiation exposure, and follow-up of any incidental findings. While there is uncertainty accompanying the limited trial evidence, it is reasonable to conclude that the invasive angiography rate following coronary CTA is not markedly different to that following perfusion imaging. Two studies showed that subsequent diagnostic testing was more frequent in subjects receiving CTA. Studies have differed in which treatment strategy results in higher overall radiation exposure. Incidental findings following coronary CTA are common and lead to further testing, but the impact of these findings on subsequent health outcomes is uncertain.

Stable Patients with Angina and Suspected Coronary Artery Disease

Before the introduction of coronary CTA, the initial noninvasive test in a diagnostic treatment strategy was always a functional test. The choice of functional test is based on clinical factors such as gender, electrocardiogram (ECG) abnormalities, and chest pain characteristics. Patients with suspicious findings are often referred to invasive angiography. When disease is detected, treatment alternatives include medical therapy or revascularization (PCI or coronary artery bypass graft [CABG] surgery). Which approach to adopt is based on the extent of anatomic disease, symptom severity, and evidence of ischemia from functional testing, noninvasive testing, or more recently, fractional flow reserve obtained during invasive angiography. A difficulty in evaluating a non-invasive diagnostic test for CAD is that it is part of testing and treatment strategy. The most informative and convincing evidence would accordingly compare outcomes following an anatomic-first (coronary CTA) and functional-first (e.g., perfusion imaging, stress echocardiography) strategies. Lacking direct comparative evidence, the steps or links in the testing-treatment pathway must be examined including diagnostic accuracy, need for invasive angiography following a non-invasive test, prognosis after a negative test, and likely outcomes of treatment based on information provided by the test.

A literature search of the MEDLINE database through September 2012 was conducted. Relevant studies identified included multicenter studies comparing diagnostic performance of
coronary CTA to angiography for evaluation of native arteries, studies of incidental findings, radiation exposure, prognosis, and studies of downstream or subsequent testing—all important considerations when comparing coronary CTA in the diagnostic-treatment pathway to alternatives.

**Diagnostic Accuracy**

Four multicenter studies evaluated the diagnostic accuracy of coronary CTA employing invasive angiography as referent standard. All patients enrolled in the 4 studies were scheduled for invasive coronary angiography (ICA); the population of interest here are patients at intermediate risk only, a minority of whom would proceed to ICA.

**ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography)** compared coronary CTA to ICA in 230 of 245 individuals experiencing typical or atypical chest pain referred for non-emergent ICA. (22) Three readers blinded to ICA results interpreted coronary CTA scans. Of the 143 normal coronary CTA scans, ICA was normal in 142 (negative predictive value [NPV] 99%); the false-positive rate was 17%. Radiation dose, prevalence of incidental non-cardiac findings, and follow-up were not reported in the report. Using a 50% stenosis cutoff, disease prevalence was 25%, with 13% having 70% or greater stenosis. Estimated pretest disease probability was not reported.

**CORE 64 (Coronary Artery Evaluation Using 64-Row Multidetector Computed Tomography Angiography)** evaluated 405 individuals referred for ICA to evaluate suspected CAD at 9 centers. (23) There were 89 patients (22%) excluded from analyses due to Agatston calcium score greater than 600; results from 291 of 316 remaining individuals were analyzed. Coronary CTA was the initial diagnostic test, and investigators and physicians were subsequently blinded to coronary CTA results. Sensitivity was 85%, NPV, 83%, and false-positive rate, 10%. Coronary CTA radiation dose was 13.8 ± 1.2 mSv for men and 15.2 ± 2.4 mSv for women. Noncardiac findings were reported to the treating physician but were not described in the report. Disease prevalence was 56%, using a 50% stenosis cutoff. Pretest disease probability was not reported.

Meijboom et al. (24) evaluated 433 individuals, aged 50 to 70 years, seen at 3 university hospitals referred for ICA to evaluate suspected stable or unstable angina; 371 consented to participate and 360 completed the study. Tests were interpreted in blinded fashion. Sensitivity was 99%, NPV, 97%, and false-positive rate, 36%. Estimated radiation exposure based on instrument parameters ranged from 15 to 18 mSv. The frequency of noncardiac findings was not reported. Disease prevalence was 68%, using a 50% stenosis cutoff; pretest probability was not reported.

Chow et al. (25) gained consent from 181 patients and examined 169 from 250 eligible patients referred to ICA for evaluation of CAD (n=117) or structural heart disease (n=52). Four centers evaluated differing numbers of patients—102 (60.3%), 40 (23.7%), 16 (9.5%), and 11 (6.5%), respectively. Overall sensitivity for obstructive CAD was 81%, NPV, 85%, and false positive rate, 7%. Performance characteristics differed substantially and significantly by site. The center enrolling the majority of patients reported sensitivity, specificity, NPV and positive predictive values (PPVs) of 93%, 93%, 91%, and 95%, respectively; the other 3 centers 67%, 93%, 92%, and 71%. Average radiation exposure was estimated to be 11.0 ± 6.8 mSv. Disease prevalence was 53%, using a 50% stenosis cutoff and mean estimated pretest probability of CAD 47%.
There was variability in coronary CTA diagnostic accuracy reported from these multicenter studies spanning different disease prevalence populations. The lower sensitivity reported by Chow et al. (25) is of note alongside the considerable between-center variability. In contrast to the others, the study used visual ICA assessment as a referent standard. While arguably, visual assessment is most often used in practice, it is prone to imprecision. (26, 27) Although Chow et al. (25) reported high inter-observer agreement for ICA (kappa=0.88), Zir et al. (27) found 4 experienced observers agreed 65% of the time whether a stenosis exceeded 50% in 20 angiograms. Finally, the small number of patients enrolled from 3 centers relative to overall annual coronary CTA volume (center 1—102/1,325; 2—40/1,539; 3—11/1,773; 4—16/268) might reflect sampling variability (screening procedures or whether consecutive patients were approached was not reported).

Patient populations included in each study varied, as did disease prevalence. Estimates of pretest disease probability were not reported except by Chow et al., (25) but given that all patients were referred to ICA, they were presumably at least in the upper intermediate probability range. With those caveats, the studies support concluding that coronary CTA is sensitive for detecting stenoses in samples with varying disease prevalences. Sensitivities are at least as good those cited for other noninvasive tests; false positives are not uncommon, but the rate is similar to other noninvasive tests. However, as suggested by Chow et al. (25) sensitivity and specificity achieved in the real world are likely lower than those reported under more carefully controlled conditions. These results are, however, subject to verification bias, (28) as all patients were referred for ICA. The performance characteristics reported from these studies, as well as for accuracy studies of some non-invasive test among patients selectively referred to ICA, might differ in practice when the test is used in patients not referred. In comparison, a recent meta-analysis including smaller single center studies (42 total) estimated pooled sensitivity and specificity of 98% and 85%. (29) Finally, radiation exposure reported in these studies is consistent with others using retrospective gating. Current prospective gating techniques will result in lower radiation doses.

Incidental Findings

Nine studies using 64+ slice scanners were identified. (30-38) Incidental findings were frequent (26.6% to 68.7%) with pulmonary nodules typically the most common and cancers rare (approximately 5/1,000 or less). Aglan et al. (30) compared the prevalence of incidental findings when the field of view was narrowly confined to the cardiac structures seen when the entire thorax was imaged. As expected, incidental findings were less frequent in the restricted field (clinically significant findings in 14% versus 24% when the entire field was imaged).

Prognosis

Hulten et al. (39) performed a meta-analysis of 18 studies (n=9,592) with 3 or more months' follow-up (median 20 months) enrolling patients with suspected CAD (mean age 59 years, 58% male). Annualized death or myocardial infarction (MI) rates after a normal coronary CTA (no identified stenosis >50%) was 0.15%. The pooled rate included 2 studies of EBCT and 4 that utilized 16 slice scanners; most events in the normal group occurred in one of the EBCT studies. Bamberg et al. (40) pooled results from 9 studies (n=3,670) enrolling ≥100 patients with ≥1 year follow-up enrolling patients with suspected CAD (mean age 59.1±2.6 years, 63% male). The pooled annualized event rate (all-cause and cardiac death, MI, unstable angina, revascularization) was 1.1% following a coronary CTA without evidence of significant stenosis; in the 38% of patients without evidence of any atherosclerotic plaque, the annual event rate...
0.4%. In comparison, Metz et al. (41) performed a meta-analysis of event rates following a negative MPI and stress echocardiography. The pooled annual cardiac death and MI rates following negative MPI (17 studies; 8,008 patients) and stress echocardiography (4 studies; 3,021 patients) were 0.45% and 0.51%, respectively.

**Subsequent or Downstream Testing**

Whether tests are used to replace, or add to, others currently in use are relevant. Few studies have addressed this issue. In an analysis of 2006 data from patients without CAD, as recorded in claims, Min et al. (42) found that following MPI, 11.6% of 6,588 patients underwent subsequent MPI, coronary CTA, or invasive angiography; following coronary CTA, 14.6% of 1,647 patients underwent one of those tests. A study of Medicare claims from 2005-2008 showed different results. (43) Compared with MPI, patients undergoing CTA had a higher likelihood of subsequent cardiac catheterization (22.9% vs. 12.1%), and higher rates of percutaneous coronary procedures and bypass surgery. Aggregate healthcare spending was higher in subjects who had CTA. More recently, Cheezum et al. (44) retrospectively identified 241 symptomatic patients without known CAD undergoing coronary CTA and matched them by age and gender to 252 also symptomatic patients undergoing MPI. Downstream testing was less frequent following coronary CTA than MPI (11.5% vs. 17.0%), as well as ICA (3.3% vs. 8.1%). Finally, coronary CTA and ICA in Ontario are centralized to a single academic center in Ottawa, which allowed investigators to examine coronary CTA accuracy concurrent with the impact on ICA referrals (45). Consecutive patients (n=3,538) were evaluated by ICA during 14 months before and in the 12 months after (n=3,479) coronary CTA introduction. The rate of normal ICA decreased from 31.5% before to 26.8% after coronary CTA introduction (p=0.003). During the same period at 3 other centers without coronary CTA programs, normal ICA rates increased from 30.0% to 31.0%. Given that all these studies are observational, it is difficult to make solid conclusions on the impact of use of CTA on overall utilization of subsequent diagnostic and therapeutic procedures.

**Radiation Exposure**

Exposure to ionizing radiation increases lifetime cancer risk. (BEIR VII, 46) Three studies have estimated excess cancer risks due to radiation exposure from coronary CTA. (6, 7, 47) Assuming a 16-mSv dose, Berrington de Gonzalez et al. (47) 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. (7) 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. (6) 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. (48) In a study of patients undergoing an axial scanning protocol, mean radiation dose was 3.5 mSv, and produced equivalent ratings of image quality compared to helical scan protocols, which had much higher mean radiation doses of 11.2 mSv. (49)

Although indirectly related to coronary CTA, Eisenberg et al. (8) 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).

Conclusions. A number of multicenter studies have evaluated the diagnostic accuracy of CTA for diagnosing coronary ischemia in an outpatient population. In general, these studies report high sensitivity and specificity, but there is some variability in these parameters across studies. Use of CTA in this situation does not have the same advantage of improving the efficiency of diagnosis as it does in the emergency setting. The risk/benefit ratio for this test depends on the diagnostic accuracy, the impact of incidental findings, and the amount of radiation exposure. Given the uncertainty in these parameters, it is not possible to conclude that the use of CTA in this setting leads to improved outcomes compared to alternative strategies. Therefore CTA is considered investigational when used in the outpatient setting to evaluate patients with suspected cardiac ischemia.

Other Diagnostic Uses of Coronary CTA

Given its ability to define coronary artery anatomy, there are many other potential diagnostic uses of coronary CTA including patency of coronary artery bypass grafts, in-stent restenosis, screening, and preoperative. Evaluating patency of vein grafts is generally less of a technical challenge due to their size and lesser motion during imaging. In contrast, internal mammary grafts may be more difficult to image due to their small size and presence of surgical clips. Finally, assessing native vessels distal to grafts presents difficulties due to their small size and when calcifications are present. For example, a 2008 meta-analysis including results from 64-slice scanners, reported high sensitivity 98% (95% CI: 95 to 99; 740 segments) and specificity 97% (95% CI: 94 to 97). (50) Other small studies have reported high sensitivity and specificity. (51, 52) Lacking are multicenter studies demonstrating likely clinical benefit, particularly given the reasonably high disease prevalence in patients evaluated. Use of coronary CTA for evaluation of in-stent restenosis presents other technical challenges—motion, beam hardening, and partial volume averaging. Whether those challenges can be sufficiently overcome to obtain sufficient accuracy and impact outcomes has not been demonstrated. The use for screening a low-risk population was recently evaluated in 1,000 patients undergoing coronary CTA compared to a control group of 1,000 similar patients. (53) Findings were abnormal in 215 screened patients. Over 18 months’ follow-up, screening was associated with more invasive testing, statin use, but without difference in cardiac event rates. Lastly, coronary CTA for preoperative evaluation before non-cardiac surgery has been suggested, evaluated in a only small studies, and lacking demonstrable clinical benefit.

Summary

In patients presenting to emergency settings with acute chest pain that is possibly cardiac in origin and no known history of coronary artery disease (CAD), the net health outcome following coronary contrast-enhanced computed tomography (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. In addition, it is a more efficient strategy in the emergency setting compared to alternative approaches. 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.

For other indications such as evaluation of patients with stable chest pain, the balance of potential benefits and harms remains uncertain owing largely to the lack of direct comparative evidence. A fundamental difficulty with current, albeit substantial indirect evidence surrounding coronary CTA is that decision making has historically relied on a strategy of functional non-invasive testing followed by invasive angiography to define anatomy. The individual studies and systematic reviews of coronary CTA accuracy for anatomic obstruction indicate sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) as good as or better than with other noninvasive tests. There is limited evidence that coronary CTA may decrease the rate of normal invasive coronary angiography (ICA) in the diagnostic evaluation of CAD. Studies in representative populations that examined the frequency of repeated testing are lacking. Noncardiac findings are frequent, but the consequences as benefits and harms have received limited scrutiny. Evidence indicates radiation exposure with current scanners utilizing reduction techniques is lower than with myocardial perfusion imaging (MPI). Because of the uncertainty regarding whether outcomes are improved with CTA compared to alternative tests, the use of CTA for this patient population is considered investigational.

Practice Guidelines and Position Statements

Appropriate use criteria (54-56) and expert consensus documents (57-59) have been published jointly by ACCF/ACR/AHA/NASCI/SAIP/SCAI/SCCT, but U.S. guidelines have not been developed. The authors of these publications state that the evidence base for CTA is not yet sufficiently robust to support clinical guideline development. The following are statements from the consensus document:

The “…overall sensitivity and specificity on a per-patient basis are both high, and the number of indeterminate studies due to inability to image important coronary segments in the select cohorts represented is less than 5%. In most circumstances, a negative coronary CT angiogram rules out significant obstructive coronary disease with a very high degree of confidence, based on the post-test probabilities obtained in cohorts with a wide range of pretest probabilities. However, post-test probabilities following a positive coronary CT angiogram are more variable, due in part to the tendency to overestimate disease severity, particularly in smaller and more distal coronary segments or in segments with artifacts caused by calcification in the arterial walls. At present, data on the prognostic value of coronary CTA using 64-channel or greater systems remain quite limited. Furthermore, no large-scale studies have yet made a direct comparison of long-term outcomes following conventional diagnostic imaging strategies versus strategies involving coronary CTA.”

“...In the context of the emergency department evaluation of patients with acute chest discomfort, currently available data suggest that coronary CTA may be useful in the evaluation of patients presenting with an acute coronary syndrome (ACS) who do not have either acute electrocardiogram (ECG) changes or positive cardiac markers. However, existing data are limited, and large multicenter trials comparing CTA with conventional evaluation strategies are needed to help define the role of this technology in this category of patients.”
NICE considers coronary CTA indicated for patients with stable chest pain, Agatston score less than 400, when the pretest likelihood is between 10% and 29%. (60)

**Medicare National Coverage**

There is no national coverage determination.

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<td>Coronary atherosclerosis of bypass graft, code range</td>
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<tr>
<td>HCPCS</td>
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<tr>
<td>ICD-10-CM (effective 10/1/14)</td>
<td>I25.10</td>
<td>Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
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<td>I25.810-I25.812</td>
<td>Atherosclerotic of coronary artery bypass graft code range</td>
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<tr>
<td>ICD-10-PCS (effective 10/1/14)</td>
<td>B221Y0Z</td>
<td>Imaging, heart, computerized tomography (CT), coronary arteries multiple, other contrast, unenhanced and enhanced</td>
</tr>
</tbody>
</table>

Index
Angiography, Computed Tomography
Computed Tomography Angiography
CTA
CT Angiography