Title: Contrast-Enhanced Coronary Computed Tomography Angiography (CCTA) for Coronary Artery Evaluation

See also: Computed Tomography to Detect Coronary Artery Calcification
CTA and MRA of the Chest (excluding the heart)
CTA and MRA of the Head, Neck, Abdomen, Pelvis, and Lower Extremities
Cardiac Computed Tomography (CT)

Professional
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January 12, 2007; July 30, 2007; January 25, 2008; January 30, 2008;
August 11, 2009; January 1, 2010; August 19, 2011; December 9, 2011;
February 26, 2013; December 31, 2013; February 4, 2015; March 2, 2016;
May 25, 2016; December 21, 2016; October 25, 2017
Current Effective Date: December 21, 2016

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Contrast-enhanced coronary computed tomography angiography (CCTA) 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, ie, non-invasive stress testing and/or coronary angiography.

DESCRIPTION

Contrast-enhanced coronary computed tomography angiography (CCTA) 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, ie, non-invasive stress testing and/or coronary angiography.

OBJECTIVE

The objective of this evidence review is to evaluate whether coronary computed tomography angiography (CCTA) improves health outcomes compared to alternative testing strategies. Three major indications for cardiac or coronary computed tomography angiography are considered: (1) evaluation of patients with acute chest pain without known coronary disease presenting in the emergency department (ED) setting, (2) evaluation of stable patients with signs and symptoms of coronary artery disease in the non-ED setting, and (3) evaluation of anomalous coronary arteries.

BACKGROUND

Coronary Artery Disease

Various noninvasive tests are used to diagnose 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, stress echocardiography with or without contrast), and others that identify the anatomic obstruction itself (coronary computed tomography angiography [CCTA], coronary magnetic resonance imaging). 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 CCTA.

**Diagnostic Testing**

Some tests will be unsuitable for particular patients. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory imaging. 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 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.

Evaluation of obstructive CAD involves quantifying arterial stenoses to determine whether significant narrowing is present. Lesions with stenosis more than 50% to 70% in diameter accompanied by symptoms are considered significant.

Contrast-enhanced CCTA is a noninvasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed computed tomography machinery to obtain detailed volumetric images of blood vessels. It has been suggested that CCTA may help rule out CAD and avoid invasive coronary angiography in patients with a low clinical likelihood of significant CAD. Also of interest is the potentially important role of nonobstructive plaques (ie, those associated with <50% stenosis) because their presence is associated with increased cardiac event rates.\(^2\) CCTA also can visualize the presence and composition of these plaques and quantify plaque burden better than conventional angiography, which only visualizes the vascular lumen. Plaque presence has been shown to have prognostic importance.

**Coronary Arterial Anomalies**

Congenital coronary arterial anomalies (ie, abnormal origin 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 (eg, syncope). There is no specific clinical presentation to suggest a coronary artery anomaly.

**Radiation Exposure**

Levels of radiation delivered with current generation scanners using reduction techniques (prospective gating and spiral acquisition) have declined substantially—typically to under 10 mSv. For example, an international registry developed to monitor CCTA radiation exposure recently reported a median of 2.4 mSv (interquartile range, 1.3-5.5).\(^3\) By comparison, radiation exposure accompanying rest-stress perfusion imaging varies by isotope used—approximately 5 mSv for rubidium 82 (positron emission tomography).
mSv for fluorine 18 fluorodeoxyglucose, 9 mSv for sestamibi (single-photon emission computed tomography), and 41 mSv for thallium; during diagnostic invasive coronary angiography, approximately 7 mSv is delivered. Electron-beam computed tomography using electrocardiogram triggering delivers the lowest dose (0.7-1.1 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 sex (greater for women). Empirical data have suggested that every 10 mSv of exposure is associated with a 3% increase in cancer incidence over 5 years.

The use of electron-beam computed tomography or helical computed tomography to detect coronary artery calcification is not addressed in this policy.

REGULATORY STATUS
Coronary computed tomography angiography (CCTA) is performed using multidetector-row computed tomography, and multiple devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) clearance process. Current machines are equipped with at least 64 detector rows. Intravenous iodinated contrast agents used for CCTA also have received FDA approval.

POLICY
A. Contrast-enhanced coronary computed tomography angiography for evaluation of patients with symptoms of stable ischemic heart disease and meeting guideline criteria (see Policy Guidelines) for a noninvasive test in the outpatient setting is considered medically necessary.

B. Contrast-enhanced coronary computed tomography angiography for evaluation of patients without known coronary artery disease and acute chest pain in the emergency room/emergency department setting is considered medically necessary.

C. Contrast-enhanced coronary computed tomography angiography for evaluation of anomalous (native) coronary arteries in patients in whom they are suspected may be considered medically necessary.

D. Contrast-enhanced coronary computed tomography angiography for coronary artery evaluation is considered experimental / investigational for all other indications.

Policy Guidelines
The 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines for the diagnosis and management of patients with stable heart disease have several class I recommendations regarding the use of noninvasive testing in patients with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general,
patients with at least intermediate risk (10-90% risk by standard risk prediction instruments) are recommended to have some kind of test, the choice of test depending on interpretability of the ECG, capability to exercise, and presence of comorbidity.

### Pretest Probability of CAD by age, gender, and symptoms*

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Gender</th>
<th>Typical / Definite Angina Pectoris</th>
<th>Atypical / Probable Angina Pectoris</th>
<th>Nonanginal Chest Pain</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 39</td>
<td>Men</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Very Low</td>
<td>Very Low</td>
<td>Very Low</td>
</tr>
<tr>
<td>40-49</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Low</td>
<td>Very Low</td>
<td>Very Low</td>
</tr>
<tr>
<td>50-59</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>Intermediate</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>&gt; 60</td>
<td>Men</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>High</td>
<td>Intermediate</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

High: >90% pretest probability. Intermediate: between 10% and 90% pretest probability. Low: between 5% and 10% pretest probability. Very low: <5% pretest probability. CAD: coronary artery disease. *Modified from the ACC/AHA Exercise Testing Guidelines to reflect all age ranges.60

### RATIONALE

This policy was originally based on a literature search of the MEDLINE database and updated with subsequent literature review and/or repeat TEC Assessments.9-11 The most recent literature review covers the period through July 21, 2017.

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility (demonstration that the diagnostic information can be used to improve patient outcomes).

### Patients with Acute Chest Pain Presenting in the Emergency Setting

#### Clinical Context and Test Purpose

The purpose of coronary computed tomography angiography (CCTA) imaging in patients with acute chest pain is to diagnose coronary artery obstruction and guide treatment decisions.

The question addressed in this evidence review is: Does CCTA improve the net health outcome of patients with acute chest pain?

The specific clinical context of each test is described briefly in the following sections. The following PICOTs were used to select literature to inform this review.

**Patients**

The relevant population of interest is patients with acute chest pain and suspected coronary artery disease (CAD) who are at intermediate to low risk.
Interventions
The intervention of interest is CCTA.

Comparators
The comparator of interest is standard emergency department (ED) care and alternative noninvasive testing including stress tests.

Outcomes
The outcomes of interest are mortality, diagnostic accuracy, and utilization of invasive coronary artery angiography.

Timing
The time of interest is in the first few days after admission to an ED and after several years or more after CCTA to evaluate event rates.

Setting
The setting is hospital EDs.

Clinical Validity
The diagnostic characteristics of CCTA have not been directly assessed in patients in the ED setting. Because patients who test negative on CCTA are discharged from care and their disease status is unknown, there is verification bias, and diagnostic characteristics of CCTA cannot be determined. The diagnostic characteristics of CCTA, previously established in other studies, were assumed to apply to patients in the ED setting and were tested in randomized trials to establish clinical utility.

Clinical Utility
In 2016, the Agency for Healthcare Research and Quality published a comparative effectiveness review on noninvasive testing for CAD.12 The review found that:

- After CCTA, clinical outcomes for patients with an intermediate pretest risk
  - were similar when compared with usual care or functional testing (low-to-moderate strength of evidence).
  - were similar when compared with single-photon emission computed tomography (SPECT) (low strength of evidence).
- After CCTA, referral for invasive coronary angiography (ICA) and revascularization
  - was more common than after functional testing (high strength of evidence).
  - was similar compared with SPECT and usual care (low strength of evidence).
- After CCTA, additional testing in the ED setting
  - was less common compared with usual care (moderate strength of evidence).
  - was more common than after SPECT (high strength of evidence).
- After CCTA, hospitalization
  - was less common compared with usual care in the ED setting (moderate to low strength of evidence).
  - was similar to functional testing in the outpatient setting (moderate strength of evidence).
Overall, the Agency for Healthcare Research and Quality review found no clear differences between strategies for clinical or management outcomes, although CCTA may lead to a higher frequency of referral for ICA and revascularization.

A 2011 TEC Assessment examined evidence for patients with acute chest pain and without known CAD. Randomized controlled trials (RCTs) and prospective observational studies were identified. RCTs of CCTA procedures conducted in ED settings are described in Table 1.

A 2007 RCT by Goldstein et al randomized 197 patients from a single center without evidence of acute coronary syndromes to CCTA (n=99) or usual care (n=98). Over a 6-month follow-up, no cardiac events occurred in either arm. ICA rates were somewhat higher in the CCTA arm. Diagnosis was achieved more quickly after CCTA.

The CT-STAT RCT evaluated a similar sample of 699 patients from 16 centers. Over a 6-month follow-up, there were no deaths in either arm; there were 2 cardiac events in the CCTA arm and one in the perfusion imaging arm. ICA rates were similar in both arms. A second noninvasive test was obtained more often after CCTA (10.2% vs 2.1%), but cumulative radiation exposure in the CCTA arm (using retrospective gating) was significantly lower (mean, 11.5 mSv vs 12.8 mSv). Time to diagnosis was shorter and estimated ED costs lower with CCTA.

A 2012 RCT (AC RIN-PA) by Litt et al also evaluated the safety of CCTA in patients in the ED. Although the trial was a randomized comparison with traditional care, the principal outcome was safety after negative CCTA examinations. No patients who had negative CCTA examinations (n=460) died or had a myocardial infarction (MI) within 30 days. Compared with traditional care, patients in the CCTA group had higher rates of discharge from the ED (49.6% vs 22.7%), shorter lengths of stay, and higher rates of detection of coronary disease.

A 2012 RCT (ROMICAT II) by Hoffmann et al compared length of stay with outcomes in patients evaluated using CCTA or usual care. For patients in the CCTA arm, mean hospital length of stay was reduced by 7.6 hours, and more patients were discharged directly from the ED (47% vs 12%). There were no undetected coronary syndromes or differences in adverse events at 28 days. However, in the CCTA arm, there was more subsequent diagnostic testing and higher cumulative radiation exposure. Cumulative costs of care were similar between groups.

A 2014 RCT (CT-COMPARE) by Hamilton-Craig et al assessed length of stay and patient costs in 562 patients presenting to the ED with low-to-intermediate risk chest pain who received CCTA or exercise stress testing. Costs within 30 days of presentation were significantly lower in the CCTA group (mean, $2193) than in the exercise testing group (mean, $2704; p<0.001). Length of stay was significantly reduced in the CCTA patients compared with the exercise testing patients. Clinical outcomes at 30 days and at 12 months did not differ.

In 2015, Linde et al reported long-term follow-up from the CATCH trial. This trial randomized 600 patients to a CCTA-guided strategy or to standard of care (SOC). For the CCTA-guided strategy, referral for ICA required coronary stenosis greater than 70%. This trial differed in design from the other trials, because patients had been discharged from the ED, and if there was intermediate stenosis (50%-70%) on CCTA, a stress test was used. The referral rate for ICA was 17% for the CCTA strategy vs 12% with SOC (p=0.1). At a median 18.7-month follow-up, a
major cardiac event was observed in 5 patients in the CCTA-strategy arm compared with 14 in the SOC group (hazard ratio [HR], 0.36; 95% confidence interval [CI], 0.16 to 0.95; p=0.04). Three other follow-up studies reported no cardiac events after a negative CCTA in the ED after 12 (N=481),20 24 (N=368),21 or 47 months (N=506).22

Table 1. RCTs Comparing CCTA With SOC in the Evaluation of Acute Chest Pain

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>N</th>
<th>Study Design</th>
<th>FU, mo</th>
<th>MI in Neg CCTA Arm</th>
<th>LOS, h (p)</th>
<th>ICA (CCTA vs Control), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldstein et al (2007)23</td>
<td>197</td>
<td>CCTA vs SPECT</td>
<td>6</td>
<td>0</td>
<td>3.4 vs 15</td>
<td>12.1 vs 7.1</td>
</tr>
<tr>
<td>Goldstein et al (2011)24</td>
<td>699</td>
<td>CCTA vs SPECT</td>
<td>6</td>
<td>0</td>
<td>2.9 vs 6.3</td>
<td>7.2 vs 6.5</td>
</tr>
<tr>
<td>Litt et al (2012)25</td>
<td>1370</td>
<td>CCTA vs SOC</td>
<td>1</td>
<td>0</td>
<td>18 vs 24</td>
<td>9.0 vs 3.5</td>
</tr>
<tr>
<td>Hoffmann et al (2012)26</td>
<td>1000</td>
<td>CCTA vs SOC</td>
<td>1</td>
<td>0</td>
<td>23.2 vs 30.8</td>
<td>11 vs 7</td>
</tr>
<tr>
<td>Hamilton-Craig et al (2014)27</td>
<td>562</td>
<td>CCTA vs SOC</td>
<td>12</td>
<td>0</td>
<td>13.5 vs 20.7</td>
<td>8.0 vs 3.8</td>
</tr>
</tbody>
</table>

Adapted from Marcus et al (2016).23

CCTA: coronary computed tomography angiography; FU: follow-up; ICA: invasive coronary angiography; LOS: length of stay; MI: myocardial infarction; Neg: negative; RCT: randomized controlled trial; SOC: standard of care; SPECT: single-photon emission computed tomography.

Section Summary: Acute Chest Pain Presenting in the Emergency Setting
The high negative predictive value of CCTA in patients presenting to the ED with chest pain permits ruling out coronary disease with high accuracy. The efficiency of the workup is improved, because patients are safely and quickly discharged from the ED with no adverse outcomes among patients with negative CCTA examinations.

Other important outcomes that require consideration when comparing technologies include ICA rates, use of a second noninvasive test, radiation exposure, and follow-up of any incidental findings. Some studies have shown that subsequent invasive testing is more frequent in patients who received CCTA. Studies have differed over which treatment strategies result in higher overall radiation exposure. Incidental findings after CCTA are common and lead to further testing, but the impact of these findings on subsequent health outcomes is uncertain.

Patients with Stable Chest Pain and Suspected CAD
Clinical Context and Test Purpose
The purpose of CCTA in patients with stable chest pain and suspected CAD is to diagnose coronary artery obstruction and guide treatment decisions.

Before use of CCTA, the initial noninvasive test in a diagnostic strategy was always a functional test. Current practice guidelines recommend a noninvasive test be performed in patients with intermediate risk of CAD. The choice of functional test is based on clinical factors such the predicted risk of disease, electrocardiogram interpretability, and ability to exercise. When disease is detected, treatment alternatives include medical therapy or revascularization (percutaneous coronary intervention or coronary artery bypass graft surgery). If revascularization is indicated, patients undergo ICA to confirm the presence of stenosis. Which approach to adopt is based on the extent of anatomic disease, symptom severity, evidence of ischemia from functional testing, and, more recently, fractional flow reserve obtained during invasive angiography. Many studies have shown that only a subset of anatomically defined coronary lesions are clinically significant and benefit from revascularization. Other studies have shown only limited benefits of treating coronary stenoses in stable patients. Thus an assessment of the diagnostic characteristics of CCTA alone is insufficient to establish clinical utility. A difficulty in evaluating a noninvasive diagnostic test for CAD is that patient outcomes depend not only on the test results, but also on
the management and treatment strategy. The most convincing evidence of clinical utility compares outcomes after anatomic-first (CCTA) and functional-first (eg, perfusion imaging, stress echocardiography) strategies.

Relevant studies reviewed here include those comparing the diagnostic performance of CCTA with angiography, studies of outcomes of patients undergoing CCTA vs alternative tests, and studies of incidental findings and radiation exposure.

The question addressed in this evidence review is: Does CCTA improve the net health outcome of patients with stable chest pain?

The specific clinical context of each test is described briefly in the following sections. The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with stable chest pain and suspected CAD who are at intermediate to low risk.

**Interventions**
The intervention of interest is CCTA.

**Comparators**
The comparator of interest is noninvasive testing including exercise electrocardiography, myocardial perfusion imaging (MPI), and stress echocardiography.

**Outcomes**
The outcomes of interest are mortality, sensitivity and specificity, MI, hospitalization, and utilization of ICA.

**Timing**
The time of interest is in the short-term to evaluate follow-up procedures after imaging and for several years or more after CCTA to determine event rates.

**Setting**
The setting is cardiology clinics equipped with standard noninvasive testing for CAD and CCTA.

**Diagnostic Accuracy**
There is a fairly large body of evidence evaluating the diagnostic characteristics of CCTA for identifying coronary lesions. The best estimate of the diagnostic characteristics of CCTA can be obtained from recent meta-analyses and systematic reviews. Table 2 shows ranges of sensitivity and specificity for functional noninvasive tests from studies of the diagnosis and management of stable angina reviewed by Fihn et al (2012). Sensitivities tended to range between 70% and 90%, depending on the test and study, and specificities ranged between 70% and 90%. For CCTA, estimates of sensitivity from various systematic reviews are considerably higher (see Table 3). The guideline statement from Fihn cited studies reporting sensitivities between 93% and 97%. A 2011 systematic review by Ollendorf et al of 42 studies showed a summary sensitivity estimate of 98% and a specificity of 85%. A 2010 meta-analysis of 8 studies...
conducted by the Health Quality Ontario showed a summary sensitivity estimate of 97.7% and a specificity of 79%.26 In the meta-analysis by Nielsen et al (2014), sensitivity rates for CCTA varied between 98% and 99% (depending on the analysis group).27

**Table 2.** Sensitivity and Specificity Estimates for Functional Noninvasive Tests From Guidelines24

<table>
<thead>
<tr>
<th>Noninvasive Test</th>
<th>Sensitivity (Range or Single Estimates), %</th>
<th>Specificity (Range or Single Estimates), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise electrocardiography</td>
<td>61</td>
<td>70-77</td>
</tr>
<tr>
<td>Pharmacologic stress echocardiography</td>
<td>85-90</td>
<td>79-90</td>
</tr>
<tr>
<td>Exercise stress echocardiography</td>
<td>70-85</td>
<td>77-89</td>
</tr>
<tr>
<td>Exercise myocardial perfusion imaging</td>
<td>82-88</td>
<td>70-88</td>
</tr>
<tr>
<td>Pharmacologic stress myocardial perfusion imaging</td>
<td>88-91</td>
<td>75-90</td>
</tr>
</tbody>
</table>

**Table 3.** Sensitivity and Specificity Estimates for CCTA From Guidelines and Meta-Analyses

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Study Type</th>
<th>Sensitivity (Range or Single Estimates), %</th>
<th>Specificity (Range or Single Estimates), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ollendorf et al (2011)25</td>
<td>Meta-analysis</td>
<td>98</td>
<td>85</td>
</tr>
<tr>
<td>Health Quality Ontario (2010)26</td>
<td>Meta-analysis</td>
<td>97.7</td>
<td>79</td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomography angiography.

**Clinical Utility**

**Randomized Controlled Trials**

For patients at intermediate risk of CAD, 3 major RCTs were identified comparing the net health outcome following a CCTA strategy with outcomes from other noninvasive testing strategies.

The PROMISE trial randomized 10,003 patients to CCTA or exercise electrocardiography, nuclear stress testing, or stress echocardiography (as determined by physician preference) as the initial diagnostic evaluation.28 For the composite end point of death, MI, hospitalization for unstable angina, or major procedural complication, the outcome rates between the 2 groups showed no statistically significant difference (HR=1.04; 95% CI, 0.83 to 1.29). CCTA also did not meet prespecified noninferiority criteria compared with alternative testing. Some clinical outcomes assessed at 12 months favored CCTA, but the differences were nonsignificant. Coronary catheterization rates and revascularization rates were higher in the CCTA group. In further prespecified analysis of PROMISE trial data, Hoffmann et al (2017) found that there was no difference in event rates (death, MI, or angina) between the groups at a median of 26 months follow-up.29 However, CCTA had better discriminatory ability than functional testing to predict events (eg, in categories of normal, mildly abnormal, moderately abnormal, and severely abnormal) in patients who had nonobstructive CAD (p=0.04). When the Framingham Risk Score was added to functional testing results, there was no significant difference in prognostic capability between the approaches (p=0.29).

In the SCOT-HEART trial, 4146 patients were randomized to CCTA plus SOC or SOC alone. The primary end point was the change in the proportion of patients with a more certain diagnosis (presence or absence) of angina pectoris.30 Secondary outcomes included death, MI, revascularization procedures, and hospitalizations for chest pain. Analysis of the primary outcome showed that patients who underwent CCTA had an increase in the certainty of their diagnosis relative to those in usual care (relative risk, 1.79; 95% CI, 1.62 to 1.96). Regarding health outcomes, the rates of heart disease death and MI were lower with CCTA (1.3% vs 2.0%);
HR=0.62; p=0.053), but results were of marginal statistical significance. In 2017, Williams et al reported on symptoms and quality of life for participants in the SCOT-HEART trial. Symptoms improved in both groups; however, improvements in symptoms and quality of life at 6 months were lower in patients in the CCTA arm than the functional testing arm. This outcome was due primarily to patients who were diagnosed with moderate CAD or had a new prescription of preventative therapy compared with patients diagnosed with normal coronary arteries or who had their preventative therapy discontinued.

The CAPP trial (2015) randomized 500 patients with stable chest pain to CCTA or exercise stress testing. The primary outcome was the change difference in scores of Seattle Angina Questionnaire domains at 3 months. Patients were also followed for further diagnostic tests and management. In the CCTA arm, 15.2% of subjects underwent revascularization. In the exercise stress testing arm, 7.7% underwent revascularization. For the primary outcome, angina stability and quality of life showed significantly greater improvement in the CCTA arm than in the exercise stress testing arm.

Nonrandomized Studies
Nonrandomized studies comparing outcomes of patients following a CCTA strategy with outcomes following other noninvasive testing strategies were also identified. Some studies have emphasized downstream utilization of diagnostic testing and procedures rather than patient outcomes.

Nielsen et al (2013) conducted an observational trial comparing patients who underwent CCTA with those having exercise stress testing. Patients had a low-to-intermediate pretest probability of CAD and presented with suspected angina. Patients were followed for 12 months after the initial test, and assessed for occurrence of major adverse events (eg, cardiac death, nonfatal MI). Subsequent utilization of cardiovascular tests and therapy were also compared between groups. Clinical outcomes were not formally compared because there were few clinical events. No deaths were reported during the follow-up period. Three patients in the exercise testing group had MIs within 12 months. For downstream test utilization, the exercise test group had greater subsequent use of perfusion imaging (9% vs 4%, p=0.03) and greater mean total 1-year costs (€1777 vs €1510, p=0.03). Rates of ICA and revascularization did not differ significantly.

Shreibati et al (2011) used Medicare claims data to compare all-cause mortality, subsequent utilization of several cardiac tests, treatment, and total costs in patients who underwent initial noninvasive testing with CCTA, stress echocardiography, MPI, or exercise electrocardiography. In this study, patients undergoing CCTA had higher rates of several types of utilization subsequent to their tests than patients undergoing MPI. The study also presented outcomes for both stress echocardiography and exercise electrocardiography, but results tended not to differ from outcomes for MPI. There were increased rates of ICA (22.9% vs 12.1%) and revascularization (11.4% vs 4.6%). Total spending and CAD-related spending were also higher for CCTA than for MPI. There was no significant difference in all-cause mortality between CCTA and MPI. Although the mortality rate for CCTA (1.05%) was slightly lower than the mortality rate for MPI (1.28%), the adjusted odds ratio showed a higher risk of mortality, which may be due to unusual confounding. However, there was a slightly lower likelihood of hospitalization for MI (adjusted OR=0.60; p=0.04).
In Min et al (2008), costs and clinical outcomes for patients undergoing initial CCTA were compared with patients undergoing initial MPI. The data source for this study was a proprietary claims database from 2 regional health plans. Utilization of medical care was lower after CCTA. Additionally, overall costs were lower, the proportion receiving ICA was lower, and the proportion receiving revascularization was lower after CCTA. Regarding clinical outcomes, the proportion with a hospitalization for angina was lower in the CCTA group. The CCTA group also had a lower rate of a combined outcome of angina or MI hospitalization (HR=0.70; 95% CI, 0.55 to 0.90).

In 2825 patients evaluated for stable angina and suspected CAD in Japan, Yamauchi et al (2012) examined outcomes after initial CCTA (n=625), MPI (n=1205), and angiography (n=950). Average follow-up was 1.4 years. In a Cox proportional hazards model adjusted for potential confounders, the relative hazard rates of major cardiac events after MPI or CCTA were lower than after angiography; annual rates were 2.6%, 2.1%, and 7.0%, respectively. Revascularization rates were higher after CCTA than MPI (OR=1.6; 95% CI, 1.2 to 2.2).

**Section Summary: Stable Angina and Suspected CAD**

A number of studies have evaluated the diagnostic accuracy of CCTA for diagnosing CAD in an outpatient population. In general, these studies have reported high sensitivity and specificity, although there is some variability in these parameters across studies. Meta-analyses of these studies have shown that, for detection of anatomic disease, CCTA has a sensitivity greater than 95%, which is superior to all other functional noninvasive tests. Specificity is at least as good as other noninvasive tests. However, the link between improved diagnosis and health outcomes is not as clear, and thus outcome studies are necessary to demonstrate the clinical utility of CCTA.

Direct clinical trial evidence comparing CCTA and other strategies in the diagnostic management of stable patients with suspected CAD has not demonstrated the superiority of CCTA in any of the single clinical trials. Clinical trials have demonstrated greater utilization of ICA and subsequent revascularization procedures after CCTA. An important problem when interpreting the clinical trials is that the comparator strategies differ: in the PROMISE and the CAPP trials, CCTA was compared with an alternative non-invasive test; in other studies, CCTA supplemented usual care (which may or may not have included a noninvasive test). These trial design differences are likely to reflect how CCTA is used in clinical practice—either as a substitute for another noninvasive test or as an adjunct to other noninvasive tests. The PROMISE trial explicitly compared CCTA with an alternative functional test as the initial diagnostic test. Although the trial did not show the superiority of CCTA and did not meet prespecified criteria for noninferiority, examination of some secondary clinical outcomes supports a conclusion of “at least” noninferiority. The results of the other randomized trials are consistent with the noninferiority of CCTA compared with other established noninvasive tests. Thus, the randomized studies indicate that outcomes of patients are likely to be similar with CCTA vs other noninvasive tests.

The nonrandomized studies of CCTA have several methodologic shortcomings, including reliance on administrative data and inability to assess and adjust fully for potential confounding. The findings have shown little difference in patient outcomes between diagnostic strategies. Downstream utilization of medical care showed variable findings.
Suspected 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 CCTA can delineate the course of these anomalous arteries, even when conventional angiography cannot.37-40 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 the impact on therapeutic decisions. Given the uncommon occurrence of these symptomatic anomalies, it is unlikely that a prospective trial of CCTA could be completed.

Incidental Findings and Radiation Exposure
A number of studies using scanners with 64 or more detector rows were identified.41-49 Incidental findings were frequent (26.6%-68.7%) with pulmonary nodules typically the most common and cancers typically more rare (~5/1000 or less). Aglan et al (2010) compared the prevalence of incidental findings when the field of view was narrowly confined to the cardiac structures with that when the entire thorax was imaged.41 As expected, incidental findings were less frequent in the restricted field (clinically significant findings in 14% vs 24% when the entire field was imaged).

Exposure to ionizing radiation increases lifetime cancer risk.50 Three studies have estimated excess cancer risks due to radiation exposure from CCTA.6,7,51 Assuming a 16-mSv dose, Berrington de Gonzalez et al (2009) estimated that the 2.6 million CCTAs performed in 2007 would result in 2700 cancers or approximately 1 per 1000.51 Smith-Bindman et al (2009) estimated that cancer would develop in 1 of 270 women and 1 of 600 men age 40 undergoing CCTA with a 22-mSv dose.7 Einstein et al (2007) employed a standardized phantom to estimate organ dose from 64-slice CCTA.6 With modulation and exposures of 15 mSv in men and 19 mSv in women, calculated lifetime cancer risk at age 40 was 7 per 1000 men (1/143) and 23 per 1000 women (1/43). However, estimated radiation exposure used in these studies was 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.52 In a 2012 study of patients undergoing an axial scanning protocol, mean radiation dose was 3.5 mSv, and produced equivalent ratings of image quality compared with helical scan protocols, which had much higher mean radiation doses of 11.2 mSv.53

Section Summary: Incidental Findings and Radiation Exposure
Although studies of incidental findings and radiation exposure raise issues regarding the potential for adverse effects of CCTA, there is insufficient evidence that the magnitude of these effects is important for ascertaining the net benefit or risk of CCTA in this setting.

Other Diagnostic Uses of CCTA
Given its ability to define coronary artery anatomy, there are many potential diagnostic uses of CCTA, including patency of coronary artery bypass grafts, in-stent restenosis, screening, and preoperative evaluation.
Patency
Evaluating patency of vein grafts is less technically challenging due to vein 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, especially when calcifications are present, due to their small size. For example, a 2008 systematic review, 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%).54 Other small studies have reported high sensitivity and specificity.55,56 Lacking are multicenter studies demonstrating likely clinical benefit, particularly given the reasonably high disease prevalence in patients evaluated.

In-Stent Restenosis
Use of CCTA for evaluating in-stent restenosis presents other technical challenges—motion, beam hardening, and partial volume averaging. Whether these challenges can be overcome to obtain sufficient accuracy and impact outcomes has not been demonstrated.

Screening
Use for screening a low-risk population was recently evaluated in 1000 patients undergoing CCTA or control intervention of 1000 similar patients.57 Findings reported in this 2011 study were abnormal in 215 screened patients. Over 18 months of follow-up, screening was associated with more invasive testing, statin use, but no difference in cardiac event rates.

Preoperative Evaluation
Use for screening in a high-risk population was evaluated in the FACTOR-64 trial, which randomized 900 subjects with diabetes to screening with CCTA or SOC.58 Patients in this trial were asymptomatic, but considered to be at high risk for CAD due to long-standing diabetes. The primary outcome was a composite of mortality, nonfatal MI, or unstable angina requiring hospitalization. At a median follow-up of 4 years, there was no significant difference between the groups for the primary outcome (CCTA, 6.2% vs control, 7.6%; HR=0.80; p=0.38).

CCTA for preoperative evaluation before noncardiac surgery has been suggested, but evaluated only in small studies and lacking demonstrable clinical benefit.

SUMMARY OF EVIDENCE
For individuals who have acute chest pain and suspected coronary artery disease in the emergency setting, at intermediate to low risk, who receive coronary computed tomography angiography (CCTA), the evidence includes several randomized controlled trials. Relevant outcomes are overall survival, morbid events, and resource utilization. Trials have shown similar patient outcomes, with faster patient discharges from the emergency department, and lower short-term costs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have stable chest pain, intermediate risk of coronary artery disease, meeting guideline criteria for noninvasive testing (ie, intermediate risk) who receive CCTA, the evidence includes studies of diagnostic accuracy of CCTA, randomized trials comparing CCTA with alternative diagnostic strategies, and observational studies comparing CCTA with alternative diagnostic strategies. Relevant outcomes are overall survival, test accuracy, morbid events, and
resource utilization. Studies of diagnostic accuracy have shown that CCTA has higher sensitivity and similar specificity to alternative noninvasive tests. Although randomized trials have not shown the superiority of CCTA over other diagnostic strategies, results are consistent with noninferiority (ie, similar health outcomes) to other diagnostic strategies. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected anomalous coronary arteries who receive CCTA, the evidence includes case series. Relevant outcomes are overall survival, test accuracy, morbidity, events, and resource utilization. Series have shown that CCTA can detect anomalous coronary arteries missed by other diagnostic modalities. Anomalous coronary arteries are rare, and formal studies to assess clinical utility are unlikely to be performed. In most situations, these case series alone would be insufficient to determine whether the test improves health outcomes. However, in situations where patient management will be affected by CCTA results (eg, with changes in surgical planning), an indirect chain of evidence indicates that health outcomes are improved. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

American College of Cardiology Foundation et al

The American College of Cardiology Foundation (ACCF) and several other medical societies issued joint guidelines for management of patients with stable ischemic heart disease in 2012 (see Table 4).24

**Table 4. Joint Guidelines on Management of Stable Ischemic Heart Disease**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Recommendation</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unknown</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Able to exercise</strong></td>
<td>“CCTA might be reasonable for patients with an intermediate pretest probability of IHD who have at least moderate physical functioning or no disabling comorbidity.”</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td><strong>Unable to exercise</strong></td>
<td>“CCTA is reasonable for patients with a low to intermediate pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity.”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>“CCTA is reasonable for patients with an intermediate pretest probability of IHD who a) have continued symptoms with prior normal test findings, or b) have inconclusive results from prior exercise or pharmacological stress testing, or c) are unable to undergo stress with nuclear MPI or echocardiography.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td><strong>Known coronary disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Able to exercise</strong></td>
<td>“CCTA may be reasonable for risk assessment in patients with S1HD who are able to exercise to an adequate workload but have an uninterpretable ECG.”</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td><strong>Able to exercise</strong></td>
<td>“Pharmacological stress imaging (nuclear MPI, echocardiography, or CMR) or CCTA is not recommended for risk assessment in patients with S1HD who are able to exercise to an adequate workload and have an interpretable ECG.”</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td><strong>Unable to exercise</strong></td>
<td>“Pharmacological stress CMR is reasonable for risk assessment in patients with S1HD who are unable to exercise to an adequate workload regardless of interpretability of ECG.”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>“CCTA can be useful as a first-line test for risk assessment in patients with S1HD who are unable to exercise to an adequate workload regardless of interpretability of ECG.”</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>
Unable to exercise

“A request to perform either a) more than 1 stress imaging study or b) a stress imaging study and a CCTA at the same time is not recommended for risk assessment in patients with SIHD.”

Regardless of patients’ ability to exercise

“CCTA might be considered for risk assessment in patients with SIHD unable to undergo stress imaging or as an alternative to invasive coronary angiography when functional testing indicates a moderate- to high-risk result and knowledge of angiographic coronary anatomy is unknown.”

CCTA: coronary computed tomography angiography; CMR: cardiac magnetic resonance; ECG: electrocardiography; IHD: ischemic heart disease; LOE: level of evidence; MPI: myocardial perfusion imaging; SIHD: stable ischemic heart disease.

In 2013, ACCF and other medical societies published appropriate use criteria for detection and risk assessment of stable ischemic heart disease.\(^5^9\) CCTA was considered appropriate for:

- Symptomatic patients with intermediate (10%-90%) pretest probability of coronary artery disease (CAD) and uninterpretable ECG or inability to exercise
- Patients with newly diagnosed systolic heart failure
- Patients who have had a prior exercise ECG or stress imaging study with abnormal or unknown results
- Patients with new or worsening symptoms and normal exercise ECG

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence has recommended CCTA as first-line testing for patients with stable angina if the clinical assessment indicates typical or atypical angina, or if clinical assessment indicates nonanginal chest pain but 12-lead resting ECG has been done and indicates ST-T changes or Q waves.\(^6^0\)

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

No U.S. Preventive Services Task Force recommendations for CCTA have been identified.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 5.

<table>
<thead>
<tr>
<th>NCT Number</th>
<th>Title</th>
<th>Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>IMAGE-HF Project I-C: Computed Tomographic Coronary Angiography for Heart Failure Patients (CTA-HF)</td>
<td>250</td>
<td>Jun 2017 (ongoing)</td>
</tr>
<tr>
<td>ISRCTN19102565</td>
<td>Rapid Assessment of Potential Heart Disease with CTCA (RAPID-CTCA)</td>
<td>2500</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT02400229</td>
<td>Diagnostic Imaging Strategies for Patients With Stable Chest Pain and Intermediate Risk of Coronary Artery Disease (DISCHARGE)</td>
<td>3546</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>Unpublished</td>
<td>Plaque Registration and Event Detection In Computed Tomography (PREDICT)</td>
<td>3015</td>
<td>Dec 2014 (unknown)</td>
</tr>
<tr>
<td>NCT02291484</td>
<td>Comprehensive Cardiac CT Versus Exercise Testing in Suspected Coronary Artery Disease (2) (CRESCENT2)</td>
<td>250</td>
<td>May 2016 (completed)</td>
</tr>
<tr>
<td>NCT01384448</td>
<td>Stress Echocardiography and Heart Computed Tomography (CT) Scan in Emergency Department Patients With Chest Pain</td>
<td>400</td>
<td>Feb 2017 (completed)</td>
</tr>
</tbody>
</table>
### Coding

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

#### CPT/HCPCS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>75574</td>
<td>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)</td>
</tr>
</tbody>
</table>

#### ICD-9 Diagnoses

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>414.00</td>
<td>Coronary atherosclerosis of unspecified type of vessel, native or graft</td>
</tr>
<tr>
<td>414.01</td>
<td>Coronary atherosclerosis of native coronary artery</td>
</tr>
<tr>
<td>414.02</td>
<td>Coronary atherosclerosis of autologous vein bypass graft</td>
</tr>
<tr>
<td>414.03</td>
<td>Coronary atherosclerosis of nonautologous biological bypass graft</td>
</tr>
<tr>
<td>414.04</td>
<td>Coronary atherosclerosis of artery bypass graft</td>
</tr>
<tr>
<td>414.05</td>
<td>Coronary atherosclerosis of unspecified type of bypass graft</td>
</tr>
</tbody>
</table>

#### ICD-10 Diagnoses (Effective October 1, 2015)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I25.10</td>
<td>Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
</tr>
<tr>
<td>I25.110</td>
<td>Atherosclerotic heart disease of native coronary artery with unstable angina pectoris</td>
</tr>
<tr>
<td>I25.111</td>
<td>Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm</td>
</tr>
<tr>
<td>I25.118</td>
<td>Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris</td>
</tr>
<tr>
<td>I25.119</td>
<td>Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris</td>
</tr>
<tr>
<td>I25.700</td>
<td>Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris</td>
</tr>
<tr>
<td>I25.701</td>
<td>Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm</td>
</tr>
<tr>
<td>I25.708</td>
<td>Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris</td>
</tr>
<tr>
<td>I25.709</td>
<td>Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris</td>
</tr>
<tr>
<td>I25.710</td>
<td>Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris</td>
</tr>
</tbody>
</table>
I25.711  Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718  Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719  Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720  Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721  Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.728  Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729  Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730  Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731  Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738  Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739  Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.790  Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791  Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798  Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799  Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I25.810  Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

REVISIONS

01-10-2006  In “Policy” section, deleted old policy and added “Computed tomographic angiography (CTA) is considered experimental/investigational for the evaluation of coronary arteries including but not limited to the following:
1. Screening for coronary artery disease (CAD), either in asymptomatic subjects or as part of a preoperative evaluation
2. Diagnosis of CAD, in patients with acute or non-acute symptoms, or after a coronary intervention
3. Delineation of a coronary artery anatomy or anomaly
Computed tomographic angiography (CTA) of other arteries may be indicated when medically necessity is properly documented.”

In “Coding”, Covered Diagnosis section added “Note: The use of any diagnosis code does not guarantee reimbursement. Medical necessity will be based on documentation in the medical record.”

In “Reference” Government Agency; Medical Society; and Other Authoritative Publications section added #3 – BCBSA, #4 – BCBSKS Medical Consultant (401) and #5 – BCBSKS
<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>09-01-2006</td>
<td>Added “Note: As of June 14, 2006, per updated review by consultant, coronary CT angiography remains experimental / investigational because of lack of adequate repeated studies. Further investigation is needed.” Consultant (MCMC – S087, Board certified in Internal Medicine, Cardiovascular Disease and Clinical Cardiac Electrophysiology) stated “There are, however, rare, highly specialized cases where a patient is at high risk of complications from coronary angiography, a properly performed SPECT nuclear stress imaging study has been somewhat positive but not definitive, where the noninvasive detection of a significant coronary lesion would lead to an invasive evaluation, in which case multislice CT angiography procedure is medically appropriate and necessary in order to exclude a lesion and prevent a high risk invasive procedure.”</td>
</tr>
<tr>
<td></td>
<td>In “Coding” CPT section added CPT codes 0145T, 0150T, and 0151T as directed by the Medical Director.</td>
</tr>
<tr>
<td></td>
<td>In “Reference” Government Agency; Medical Society; and Other Authoritative Publications section added #6, MCMC, Medical Care Ombudsman Program (MCOP), June 14, 2006, MCOP ID 1070-1753.</td>
</tr>
<tr>
<td>01-01-2007</td>
<td>Added “Note: As of June 14, 2006, per updated review by consultant, coronary CT angiography remains experimental / investigational because of lack of adequate repeated studies. Further investigation is needed.”</td>
</tr>
<tr>
<td>04-01-2007</td>
<td>In “Coding” CPT section, deleted “Consultant (MCMC – S087, Board certified in Internal Medicine, Cardiovascular Disease and Clinical Cardiac Electrophysiology) stated “There are, however, rare, highly specialized cases where a patient is at high risk of complications from coronary angiography, a properly performed SPECT nuclear stress imaging study has been somewhat positive but not definitive, where the noninvasive detection of a significant coronary lesion would lead to an invasive evaluation, in which case multislice CT angiography procedure is medically appropriate and necessary in order to exclude a lesion and prevent a high risk invasive procedure” per Medical Director.</td>
</tr>
<tr>
<td></td>
<td>In “Coding” CPT section, deleted CPT codes 0145T, 0150T, and 0151T per Medical Director.</td>
</tr>
<tr>
<td>07-30-2007</td>
<td>Updated to provide more detail about CTA technology.</td>
</tr>
<tr>
<td></td>
<td>Policy was liberalized to consider CTA medically necessary for evaluation of anomalous (native) coronary arteries in symptomatic patients when conventional angiography is unsuccessful or equivocal and when results will impact treatment. CTA remains experimental / investigational for all other indications.</td>
</tr>
<tr>
<td></td>
<td>Policy section was revised deleting: “Computed tomographic angiography (CTA) is considered experimental/investigational for the evaluation of coronary arteries including but not limited to the following: 1. Screening for coronary artery disease (CAD), either in asymptomatic subjects or as part of a preoperative evaluation 2. Diagnosis of CAD, in patients with acute or non-acute symptoms, or after a coronary intervention 3. Delineation of a coronary artery anatomy or anomaly”</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>“Note: As of June 14, 2006, per updated review by consultant, coronary CT angiography remains experimental / investigational because of lack of adequate repeated studies. Further investigation is needed.”</td>
</tr>
<tr>
<td></td>
<td>Policy section was revised adding the first two paragraphs.</td>
</tr>
<tr>
<td></td>
<td>Documentation section was added.</td>
</tr>
<tr>
<td></td>
<td>CPT codes 0146T, 0147T, 0148T, and 0149T were added for coronary anomalies.</td>
</tr>
</tbody>
</table>
• Diagnosis codes 746.85 and 746.87 were added for coronary anomalies. Codes 747, 747.10, 747.11, 747.21, 747.22, and 747.3 were deleted.

• References were updated.

Effective 01-25-2008
• Changed the name of the Policy to “Coronary CT Angiography and Calcium Scoring” from “Computed Tomographic Angiography (CTA)”

In Description section:
• Added “coronary” to the second paragraph, fifth sentence, “…suggested that coronary CTA may be…”
• Added “coronary” to the third paragraph, first sentence, “Coronary CTA has several…”

In Policy section:
• Removed the third paragraph, “Computed tomographic angiography (CTA) of other arteries may be indicated when medical necessity is properly documented.”
• Under “Documentation” added “coronary”, “All coronary CTA studies will be…”
• Under “Utilization” added “coronary”, “Coronary CTA studies will be…”

In Coding section:
• Removed CPT codes 70496, 70498, 71275, 72191 73206, 73706, 74175.
• Removed Diagnosis codes 093.0, 414.10, 415.0, 415.11, 417.0, 417.1, 417.8, 441.02, 444.1, 447.0, 447.2, 453.2, 745.0, 745.10, 745.11, 745.12, 745.19, 745.2, 745.3, 746.87, 747.20, 747.29, 747.40, 794.2, 996.1, 996.74, V12.59
• Removed Revenue Codes 32X, 34X, 35X, 40X.

Effective 01-30-2008
In Description section:
• Added “The available evidence does not provide sufficient information to permit conclusions on the effect of coronary CT angiography on health outcomes.”
• “Electron beam computed tomography (EBCT) and multi detector computed tomography (MDCT) are methods used for measurement of coronary artery calcification. Calcium scores have been investigated both as a diagnostic technique in symptomatic patients to determine the necessity of coronary angiography or in asymptomatic patients as a screening technique for coronary artery disease. Published studies do not establish a clear role for detection of coronary artery calcification by computed tomography in coronary disease risk stratification in asymptomatic or symptomatic patients, nor have any studies shown that clinical outcomes can be favorably altered by the use of computed tomography based determination of coronary artery calcification in screening for coronary artery disease”

In Policy section:
• Added “The use of computed tomography to detect coronary artery calcification is considered investigational.”

In Coding section added:
• Added CPT/HCPCS codes 0144T S8092.
• Added Diagnosis codes 414.01, V81.1.

Effective 12-15-2008
In Heading:
• Revised title from Coronary CT Angiography and Calcium Scoring to Contrast-Enhanced Computed Tomography Angiography (CTA) for Coronary Artery Evaluation.
• Added a “See also” reference to other pertinent policies.

In Description section:
• Updated terminology and discussion.

In Policy section:
• Removed “The use of computed tomography to detect coronary artery calcification is considered investigational.” See Computed Tomography to Detect Coronary Artery Calcification policy.

Added Rationale section.
In Coding section:
- Removed CPT / HCPCS codes: 0144T, S8092.
- Removed Diagnosis codes: 414.11, 414.19, 441.01, 441.03, 441.1, 441.2, 441.5, 441.3, 441.7, 441.9, 442.82, 446.7, 746.85, V81.0.
- Added Diagnosis codes: 414.02, 414.03, 414.04, 414.05.

Updated Revisions and References sections.

**Effective 08-11-2009**
- Added policy reference of Cardiac Computed Tomography (CT)

**In Rationale section:**
- Added 2009 Update

**01-01-2010**
- Added CPT Code: 75574
- Removed CPT Codes: 0146T, 0147T, 0148T, 0149T

**08-19-2011**
- In the Policy Language section:
  - In Item #1, added “using 64 slices or greater may be considered medically necessary for the following indications:
  - a. For the evaluation of chest pain syndrome in patients with intermediate pre-test probability of CAD by Framingham risk scoring (10-20%)* or by American College of Cardiology criteria ** (see policy guidelines) and ECG is uninterpretable of patient is unable to exercise or have contraindications to exercise and pharmacologic stress testing.
  - b. For the evaluation of acute chest pain in patients with intermediate pre-test probability of CAD by Framingham risk scoring (10-20%)* or by American College of Cardiology criteria** (see policy guidelines) and no ECG changes and serial enzymes are negative.
  - c. For the evaluation of chest pain syndrome in patients with uninterpretable or equivocal stress test (exercise, perfusion, or stress echo).
  - d. For the assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves.”
  - Added Item #3, “Contrast-enhanced computed tomographic angiography is considered experimental / investigational for any of the following Body mass index (BMI) greater than 40.
  - a. Inability to image at desired heart rate (under 80 beats per minute).
  - b. Persons in atrial fibrillation or with other significant arrhythmia.
  - c. Persons with extensive coronary calcification by plain film or with prior contraindications to the procedure:
  - d. Angiston score greater than 1700.”

Added Policy Guidelines.
Updated Other References.

**12-09-2011**
- Updated Description section.
- In the Policy section:
  - Added “Contrast–enhanced computed tomographic angiography for the emergency evaluation of patients without known coronary artery disease and acute chest pain is considered medically necessary.”

Updated Rationale section.
Updated Reference section.

**02-26-2013**
- Updated Description section.
- Updated Rationale section.
- Updated Reference section.

**12-31-2013**
- In Coding section:
  - Added ICD-10 Diagnosis (*Effective October 1, 2014*)
Updated Description section.
Updated Rationale section.
Updated Coding section:
- Changed effective date for ICD-10 Diagnoses to October 1, 2015.
Updated References section.

02-04-2015
03-02-2016
In Policy section:
- Removed Item 1, "Contrast-enhanced computed tomographic angiography using 64 slices or greater may be considered medically necessary for the following indications:
  a. For the evaluation of chest pain syndrome in patients with intermediate pre-test probability of CAD by Framingham risk scoring (10-20%)* or by American College of Cardiology criteria**(see Policy Guidelines) and ECG is uninterpretable or patient is unable to exercise or have contraindications to exercise and pharmacologic stress testing.
  b. For the evaluation of acute chest pain in patients with intermediate pre-test probability of CAD by Framingham risk scoring (10-20%)* or by American College of Cardiology criteria**(see Policy Guidelines) and no ECG changes and serial enzymes are negative.
  c. For the evaluation of chest pain syndrome in patients with uninterpretable or equivocal stress test (exercise, perfusion, or stress echo).
  d. For the assessment of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chambers and valves and revised to read, "Contrast-enhanced computed tomography angiography for evaluation of patients with stable chest pain and meet guideline criteria (see Policy Guidelines) for requiring a noninvasive test in the outpatient setting is considered medically necessary."
- In Item 2, removed "emergency" and added "in the emergency room/emergency department setting" to read, "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.
- Added Item 3.
- Removed previous Item 4, "Contrast-enhanced computed tomographic angiography is considered experimental / investigational for any of the following contraindications to the procedure:
  a. Body mass index (BMI) greater than 40.
  b. Inability to image at desired heart rate (under 80 beats per minute).
  c. Persons in atrial fibrillation or with other significant arrhythmia.
  d. Persons with extensive coronary calcification by plain film or with prior Angston score greater than 1700."
- In Policy Guidelines, replaced all previous verbiage with 2012 ACCF/AHA/ACP/AATS/PCNA, SCAI/STS guidelines.

Updated Rationale section.
Updated References section.
Added Appendix section.

05-25-2016
In Policy section:
- In Policy Guidelines, added Pretest Probability table.
Updated References section.

12-21-2016
Policy title changed from "Contrast-Enhanced Computed Tomography Angiography (CTA) for Coronary Artery Evaluation."
Updated Description section.
In Policy section:
In Item A, added "coronary", "symptoms of", "ischemic heart disease", "ing", and removed "chest pain" and "requiring" to read, "Contrast-enhanced coronary computed tomography angiography for evaluation of patients with symptoms of stable ischemic heart disease and meeting guideline criteria (see Policy Guidelines) for a noninvasive test in the outpatient setting is considered medically necessary."

In Item B, added "coronary" and removed "the" to read, "Contrast-enhanced coronary computed tomography angiography for evaluation of patients without known coronary artery disease and acute chest pain in the emergency room/emergency department setting is considered medically necessary."

In Item C, added "coronary" and removed "[when conventional angiography is unsuccessful or equivocal and when the results will impact treatment]" to read, "Contrast-enhanced coronary computed tomography angiography for the evaluation of anomalous (native) coronary arteries in patients in whom they are suspected may be considered medically necessary."

In Item D, added "coronary" to read, "Contrast-enhanced coronary computed tomography angiography for coronary artery evaluation is considered experimental / investigational for all other indications."

Updated Rationale section.
Updated References section.
Removed Appendix.

10-25-2017
Updated Description section.
Updated Rationale section.
Updated References section.

REFERENCES


Other References
2. MCMC, Medical Care Ombudsman Program (MCOP), May 22, 2007, MCOP ID 1074-6539.
3. Blue Cross and Blue Shield of Kansas Radiology Liaison Committee: February 2008; February 2009; February 2010; February 2011; February 2012; February 2013.
4. Blue Cross and Blue Shield of Kansas Medical Advisory Committee: April 2009; April 2010; April 2011; April 2012.