



Coronary Computed Tomographic Angiography

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**Center for Evidence-based Policy
Medicaid Evidence-based Decisions Project (MED)**

Oregon Health & Science University
3455 SW US Veterans Hospital Road
Mailstop SN-4N, Portland, OR 97239-2941
Phone: 503.494.2182
Fax: 503.494.3807

<http://www.ohsu.edu/ohsuedu/research/policycenter/med/index.cfm>

This report was prepared by:

Edgar E. Clark, MD, MHA

Center for Evidence-based Policy
Oregon Health and Science University

This report was reviewed by:

Martha Gerrity, MD, PhD, MPH

Center for Evidence-based Policy
Oregon Health and Science University

This report was reviewed by experts in the field. Names of reviewers and disposition of review comments are available upon request.

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Table of Contents

Executive Summary.....	1
Background	4
Table 1. Prevalence of coronary artery stenosis by character of chest pain.....	4
Table 2. Conditions that cause chest pain	4
Table 3. Post-test probability of obstructive CAD using the same test but varying the pre-test probability of CAD.....	5
Table 4. Costs of CCTA and ICA	7
Key Questions	8
Methods.....	8
Findings	10
Key Question #1: What is the sensitivity and specificity of CT angiography in diagnosing obstructive coronary artery disease compared to catheter-based angiography with or without clinical follow-up?	11
Key Question #2: Are there patients, situations or setting where the results of CT angiography would preclude the use of catheter-based angiography without changing clinical outcomes?..	13
Key Question #3: What are the rates of revascularization procedures, hospitalizations, coronary heart disease (CHD) events following CT angiography compared to catheter-based angiography?	15
Key Question #4: What is the evidence for harms related to CT angiography compared to catheter-based angiography?	15
Table 5. Relative amounts of radiation exposure from different sources	15
Guidelines	16
Summary	18
Policy Considerations.....	19
Appendix A. Updated Search Strategy.....	22
Appendix B. Sensitivity and specificity of CT angiography in diagnosing obstructive coronary artery disease compared to catheter-based angiography with or without clinical follow-up.....	24
Appendix C. Subgroups of patients, situations or settings where the results of CCTA would preclude the use of catheter-based angiography without changing clinical outcomes	26
Appendix D. Rates of revascularization procedures, hospitalizations and utilization of other diagnostic tests following CT angiography compared to catheter-based angiography	28

Appendix E. Summary of guidelines	29
Appendix F. Number of asymptomatic patients with true positive and false positive results on CT angiography based on prevalence of CAD in a population.....	31
Appendix G. Analysis of Select Medicare, State and Private Payor CCTA Coverage Policies	34
Appendix H. Select Medicare, State and Private Payor CCTA Coverage Policies	35
Appendix I. Relevant codes.....	55
References	56

Abbreviations Used in this Report

ACR. American College of Radiology.

ACS. Acute coronary syndrome = myocardial infarction or unstable angina.

CAD. Obstructive coronary artery disease; stenosis or blockage of the coronary arteries.

CCTA. Coronary computed tomographic angiography. Also referred to in the literature as computed tomographic coronary angiography (CTCA) or coronary CTA.

CPG. Clinical practice guideline.

CT. Computed tomography.

ED. Emergency department or emergency room.

ECG. Electrocardiogram.

ICA. Invasive coronary angiography also catheter coronary angiography.

High probability of CAD. Probability of greater than 80% or 90% (varies by author).

Intermediate probability of CAD. Probability from 10% to 90% or from 20% to 80% (varies by author).

Low probability of CAD. Probability less than 10% or 20% (varies by author).

MA. Meta-analysis.

MACE. Major adverse cardiac event—cardiac death, non-fatal myocardial infarction and coronary revascularization.

MSCT. Multiple slice computed tomography. This refers to modern CT scanner that take more than one slice at a time—in many cases for CCTA the scanners take 64 slices. The modern CT scanners are often referred to as 64 slice CT scanners.

NPI. Nuclear perfusion imaging. A nuclear medicine test to measure the distribution of a radioactive tracer in the myocardium or the regional functioning of the myocardium. This is also referred to as stress NPI and SPECT NPI.

PCI. Percutaneous coronary intervention; this normally refers to placement of a stent in the coronary artery.

RCT. Randomized controlled trial.

Sensitivity. The ability of a test to identify correctly people with a condition. A test with high sensitivity will nearly always be positive for people who have the condition (the test has a low rate of false-negative results). Sensitivity is also known as the true-positive rate.

Specificity. The ability of a test to identify correctly people without a condition. A test with high specificity will rarely be wrong about who does NOT have the condition (the test has a low rate of false-positive results). Specificity is also known as the true-negative rate.

SR. Systematic review.

SPECT. Single photon emission computed tomography; a nuclear medicine test usually used to

perform nuclear perfusion imaging (NPI).

Stress ECG, Stress Echo, Stress SPECT. Stress refers to tests that are performed after a period of exercise on a treadmill.

TA. Technology assessment.

Executive Summary

Background

Coronary computed tomographic angiography (CCTA) is a diagnostic imaging test that uses a computed tomographic (CT) scanner to non-invasively image the coronary arteries of the heart. Since obstructive coronary artery disease (CAD) is common in the United States (US) adult population and is responsible for most of the heart attacks, the ability to identify stenosis of the coronary arteries in patients with chest pain becomes important. Coronary computed tomographic angiography can be used in place of other intermediate tests such as stress electrocardiogram (ECG), stress nuclear perfusion imaging (NPI) and stress echocardiography (ECHO) to either increase or decrease the likelihood of CAD as the cause of chest pain. In contrast to CCTA which provides anatomic information about the coronary arteries, these tests evaluate myocardial ischemia (indicators that the heart muscle is not receiving adequate blood flow). The development of multi-slice CT scanners has led to increased use of CCTA with nearly half of all cardiology practices in the US leasing or owning cardiac CT equipment. Advocates of CCTA recommend it for patients with low to intermediate risk of CAD who present with acute onset of chest pain (primarily in the emergency department setting) and with stable chest pain suggestive of CAD (primarily in the outpatient setting). Additionally CCTA is being advocated for patients with high risk of CAD and atypical chest pain, evaluation of patients with symptoms after coronary stent placement and screening of asymptomatic patients with high risk of CAD.

Both patient selection criteria and equipment capabilities affect the diagnostic efficacy of CCTA. Radiation dose and financial costs for CCTA are significant.

Methods

The key questions addressed in this review include:

Key Question #1: What is the sensitivity and specificity of CT angiography in diagnosing obstructive coronary artery disease compared to catheter-based angiography with or without clinical follow-up?

Key Question #2: Are there patients, situations or setting where the results of CT angiography would preclude the use of catheter-based angiography without changing clinical outcomes?

Key Question #3: What are the rates of revascularization procedures, hospitalizations and utilization of other diagnostic tests following CT angiography compared to catheter-based angiography?

Key Question #4: What is the evidence for harms related to CT angiography compared to catheter-based angiography?

A search of the MED clinical evidence core sources was done to identify systematic reviews (SRs), meta-analyses (MAs), technology assessments (TAs), and clinical practice guidelines (CPGs). A MEDLINE search was done to identify studies published from June 2009, the last search date for a previously identified high quality SR, through February 2010. Our search

located two SRs, one TA that includes a SR, one randomized controlled trial (RCT) and 13 observational studies. Five guidelines were identified.

Findings

Patient and technical factors affect the use and quality of CCTA. Patients selected for CCTA: 1) should not be obese; 2) should not have arrhythmias or heart rates more than 65 beats per minute; 3) should be able to hold their breath for more than 20 seconds; 4) should be able to tolerate a standard dose of contrast material; and 5) should not have significant coronary artery calcifications. Multi-slice CT scanners should have at least 64 slices to perform CCTA adequately. The performance and interpretation of CCTA requires special training, and a minimum of 50 cases per year is recommended to maintain competence in the procedure.

Coronary computed tomographic angiography has a very high sensitivity ($\geq 97\%$) and moderate to moderately high specificity (72-93%) for the detection of coronary artery stenosis, based on moderate quality evidence. A CCTA test sensitivity of 97% means it will detect almost all (97%) of those who have at least one obstructed coronary artery, and only miss 3% of such patients. Thus if the CCTA test is negative it will very likely be a "true negative" and the patients can be sent home. On the other hand, a CCTA test specificity of 72% - 93% means that in a population of patients without obstructive CAD the test will only be negative 72% to 93% of the time. In the other 7% to 28% of patients without obstructive CAD, it will be a falsely positive test. Practically speaking, a positive CCTA test will often require further testing in order to determine if it is a true positive test or a false positive test. These results can be further influenced by the prevalence of obstructive CAD in the population on which the test is used, as described in the body of the report.

These performance characteristics support the use of CCTA to "rule out" obstructive CAD in emergency department (ED) patients with acute chest pain and normal ECGs and initial cardiac enzymes, and in outpatients with stable chest pain, a population with low to intermediate probability of obstructive CAD. Coronary computed tomographic angiography in these situations can be used to identify those patients with no CAD (i.e., negative CCTA in a patient with low to intermediate [pre-test] probability of CAD), so they can be safely discharged from the ED without further evaluation. This is substantiated by one small RCT (n = 197) and 7 observational studies suggesting that *emergency room patients with low to intermediate pre-test probability of CAD and a negative CCTA do not have increased cardiac events over the subsequent year.*

In patients with low to intermediate risk of CAD, CCTA appears to have better diagnostic accuracy than stress ECG and stress NPI, based on low to moderate quality evidence. A single, poor quality, before and after study suggests that CCTA may reduce the number of subsequent tests including stress NPI and ICA. A number of validated clinical prediction rules exist that clinicians can use to assess the [pre-test] probability of obstructive CAD prior to ordering a CCTA.

Although two specialty-based guidelines find CCTA "appropriate" for patients with chest pain and a high risk of CAD, and for screening of high risk asymptomatic patients, other guidelines

recommend against these uses. We found no studies that specifically address these uses of CCTA. Moreover, the pre-test probabilities of CAD in these patient groups might result in a number of false negatives (in symptomatic patients at high risk of CAD) and false positives (in asymptomatic patients at low to intermediate risk of CAD).

Limitations of the Evidence

The overall quality of evidence for the diagnostic accuracy of CCTA is moderate due to moderate risk of bias from the use of convenience samples of patients already scheduled for ICA. Patients scheduled for ICA are likely to have a higher (pre-test) probability of CAD than patients who would receive CCTA in practice. This causes spectrum bias. The estimates of sensitivity and specificity reported in these studies may be higher than would be expected for a more typical patient population undergoing CCTA. The evidence on the effect of CCTA on subsequent cardiac diagnostic testing and cardiac events is from one small fair quality RCT and 13 cohort and case series studies of poor to good quality.

Background

Clinical overview

Epidemiology of coronary artery disease: In the United States (US), heart disease is the leading cause of death for both men and women, with more than one out of four deaths attributable to heart disease (Center for Disease Control and Prevention [CDC] 2010). Coronary artery disease (CAD), which is the most common type of heart disease, was the cause of 445,687 US deaths in 2005 (CDC 2010). It is estimated that 785,000 US adults in 2009 had new myocardial infarctions (heart attacks), with 470,000 US adults having experienced recurrent attacks (Lloyd-Jones 2009). Caucasian and African Americans have the highest percentages of deaths due to heart disease, 27.2% and 25.8% respectively (CDC 2010). Although CAD is the most common form of heart disease, the prevalence of obstructive CAD (stenosis of 50% or more) varies based on age, sex, and symptoms.

Prevalence of obstructive CAD is greater for males than females and increases with age. For example, in asymptomatic individuals, the prevalence ranges from 0.3% for young women to 12.3% for men over 60 years. The prevalence (or pre-test probability) of obstructive CAD also varies depending on the characteristics of the chest pain (Table 1).

Table 1. Prevalence of Coronary Artery Stenosis by Character of Chest Pain*

Character of chest pain	Prevalence of coronary stenosis (± standard error)
Typical angina 1) substernal pressure like chest discomfort 2) provoked by exertion or emotional stress and 3) relieved by rest or nitroglycerin	88.9% (0.7%)
Atypical Angina Chest pain that meets two of the three criteria for “typical” angina (above)	49.9% (1.1%)
Non-anginal chest pain Chest pain that meets one or none of the criteria for “typical” angina (above)	16.0% (1.2%)

* Based on coronary catheterization data reported in Diamond (1979)

The variability in prevalence of CAD based on the character of the chest pain is likely due to the fact that a variety of conditions cause chest pain. Table 2, adapted from Panju (1998), lists common conditions that cause chest pain.

Table 2. Conditions that Cause Chest Pain

Cardiac Causes of Chest Pain	Non-cardiac Causes of Chest Pain
Ischemic Angina Unstable angina Myocardial infarction	Gastroesophageal Gastroesophageal reflux (GERD) Esophageal spasm Peptic ulcer disease

Cardiac Causes of Chest Pain	Non-cardiac Causes of Chest Pain
Non-ischemic Pericarditis Valvular heart disease Aortic dissection	Non-gastroesophageal Pneumothorax Pulmonary Embolism Musculoskeletal Somatoform (panic attack)

Diagnosis of CAD: Because the clinical diagnosis of CAD by history, physical examination and resting ECG alone can be difficult, a number of tests have been developed to aid in earlier and more accurate diagnosis. These tests have included clinical risk scores such as the Duke scores (Bayliss 2002; Gibbons 1999; Pryor 1983, 1993), TIMI risk score (Hess 2010, Than 2011), stress ECG testing, stress nuclear perfusion imaging (NPI) and stress echocardiography (ECHO). The purpose of these tests is to either increase or decrease the likelihood of CAD as the cause of chest pain. Stress ECG, NPI and ECHO are sometimes called functional tests since they attempt to link the symptoms of chest pain with evidence of myocardial ischemia. Coronary computed tomographic angiography (CCTA) is another intermediate test that may be substituted for these tests. However, *CCTA is considered a structural or anatomic test. It can only determine the location and extent of obstruction of a coronary artery; it cannot link chest pain symptoms to the obstructions.*

An important concept in understanding how these tests are employed is the relationship of test sensitivity, specificity, pre-test probability and post-test probability. *The probability of a patient having a condition after completion of a test is related to the prevalence of the condition in the population (and/or pre-test probability based on risk assessment) and to the sensitivity and specificity of the test itself.* Table 3 gives results for four hypothetical patients coming from populations with different prevalence of CAD (5%, 16%, 50% and 89%) and a test with a sensitivity of 70% and specificity of 90%, based on the example in Diamond (1997).

Table 3. Post-test Probability of Obstructive CAD Using the Same Test but Varying the Pre-test Probability of CAD

Pre-test probability (prevalence of disease in the population)	Sensitivity*	Specificity*	Post-test probability if test "positive"	Post-test probability if test "negative"
5%	70%	90%	25%	2%
16%	70%	90%	57%	6%
50%	70%	90%	88%	25%
89%	70%	90%	98%	73%

* These values are *not* for CCTA. Sensitivity and specificity of CCTA are described in the findings.

This concept is important because the *pre-test probability and/or prevalence of a condition can have an important impact on the probability of disease after the test result is known (post-test probability).* Many people presenting with chest pain have a low pre-test probability of CAD (e.g., 5%); a positive test result increases the probability of CAD (25% in the example) and may

justify additional testing. A negative test result in patients with a low pre-test probability decreases the probability of CAD to 2%, effectively “ruling out” CAD and allowing discharge of the patient, or pursuit of another diagnosis. In contrast, for a person presenting with chest pain and an intermediate pre-test probability of CAD (e.g., 50%), a negative test will have a post-probability of CAD of 25%. Although a negative test result lowered the probability of CAD from 50% to 25%, a 25% probability may still be high enough to warrant further testing.

Invasive coronary angiography (ICA): Invasive coronary angiography (ICA) is a procedure used to visualize the coronary arteries. The process involves inserting a catheter into a blood vessel in the upper leg or arm and positioning the tip of the catheter at the orifice of a coronary artery. A contrast medium that is visible on x-ray is then injected, opacifying the coronary artery and allowing identification of coronary artery stenosis (narrowing) or blockage. Invasive coronary angiography is the current gold (or reference) standard for the detection of coronary stenosis or blockage. Most experts consider a narrowing of the coronary artery of more than 50% to be significant and a narrowing of more than 70% to warrant treatment with coronary revascularization (stenting or bypass). While major complications are rare, risks from coronary angiogram include heart attack, stroke, injury to the catheterized artery, irregular heart rhythms, allergic reaction to the contrast or medications used during the procedure, a tear in heart or artery, kidney damage, excessive bleeding, infection, blood clots and/or exposure to radiation from x-rays (Mayo Clinic 2011a).

Coronary computed tomographic angiography (CCTA): Computed tomographic coronary angiography is a noninvasive procedure used to determine whether obstructive CAD is present. Computed tomographic coronary angiography uses a CT scanner to produce cross-sectional x-ray images (slices) of the heart, which, in turn, are computer processed to create three dimensional images of the heart and its arteries. Similarly to ICA, CCTA uses an intravenous contrast agent that opacifies the coronary arteries permitting analysis of their lumens and detection of stenosis or blockage. Although it is noninvasive, risks of CCTA can include allergic and toxic reactions to contrast material and exposure to radiation (Mayo Clinic 2011b). As one of several intermediate tests to diagnose CAD, CCTA may be used in place of (or in addition to) stress ECG, stress NPI and stress echocardiography. *Coronary computed tomographic angiography produces anatomic information about the coronary arteries whereas the other non-invasive tests provide functional information about the myocardium, heart muscle, (presumably due to reductions in coronary artery flow or ischemia). In some diagnostic settings, functional information may be more valuable than anatomic information from CCTA and vice versa* (Institute for Clinical and Economic Review [ICER] 2008, Ollendorf 2010).

Computed tomographic coronary angiography has rapidly evolved over the past ten years. The coronary arteries which measure less than one centimeter in diameter are situated on the surface of the heart. The heart is moving both with respiration and with cardiac contractions. As such, the coronary arteries are moving in complex directions over the period of fractions of a second. The small size and complex motion of the coronary arteries require the acquisition of CT images of high spatial and temporal resolution. Multi-slice CT scanners obtain more than one slice per scanning cycle; current scanners obtain 64, 128 or 256 slices per cycle. This means that at least 64 slices can be obtained per cycle (e.g., every one second). The slices can

therefore be as narrow as one millimeter thick and the entire heart can still be scanned in ten to fifteen seconds. By gating image acquisition only during the diastolic portions of the cardiac cycle (when motion of the heart is minimal), multi-slice scanners of at least 64 slices allow sufficient spatial and temporal resolution to produce diagnostic images of the coronary arteries. Of note, there are several patient conditions that *preclude* the performance of CCTA or *limit the quality* of CCTA, as listed below. The percentage of patients unable to have CCTA because of these conditions is not known; the local percentage would be important for anyone planning to use CCTA as the first diagnostic test (following the history, physical examination, EKG, and cardiac enzymes) for patients with low to intermediate risk of CAD.

- Contrast allergy or renal insufficiency prevents the use of contrast agents.
- Patient obesity limits the quality of the images.
- Inability to hold one’s breath for at least 20 seconds results in excessive respiratory motion.
- Cardiac arrhythmias and heart rates of greater than 60 beats per minute make cardiac gating difficult and thus increase cardiac motion.
- Coronary artery calcifications create artifacts that interfere with analysis of the coronary artery lumens.

Policy context

The technological evolution of CCTA has resulted in substantial growth in its use. Findings from a 2009 survey indicate that *nearly half of US-based cardiology practices now own or lease cardiac CT equipment* (Ollendorf 2010). In addition, CCTA is currently being advocated in the following clinical settings:

- Evaluation of stable chest pain in patients with low to intermediate probability of CAD;
- Evaluation of patients presenting to the emergency department (ED) with chest pain; and no evidence of myocardial infarction on ECG or cardiac enzyme blood tests;
- Evaluation of patients with high probability of CAD and atypical clinical presentation or non-diagnostic stress ECG;
- Evaluation of symptomatic patients after cardiac stent placement; and
- Screening of symptomatic patients who have intermediate to high risk of CAD.

The total *costs for CCTA* range from \$300 to \$800 per procedure, with Medicare reimbursement rates at \$508 per CCTA (Halpern 2010; Ladapo 2009). In comparison, ICA is estimated to cost \$1750 to almost \$3000 per procedure, with Medicare reimbursement rates of \$2948 per cardiac catheterization (Halpern 2010; Ladapo 2009). Halpern (2010) broke down the Medicare fee schedules for both CCTA and cardiac catheterization (Table 4).

Table 4. Costs of CCTA and ICA

Procedure	CPT Codes	Medicare Fee (US \$)
Coronary CT Angiography (CCTA)		
Professional fee	0146T	\$186
Technical fee	0146T	\$322
Total	0146T	\$508

Procedure	CPT Codes	Medicare Fee (US \$)
Cardiac catheterization (ICA)		
Professional fee	93510, 93543, 93556, 93545	\$354
Technical fee		\$2594
Total		\$2948

Key Questions

1. What is the sensitivity and specificity of CT angiography in diagnosing obstructive coronary artery disease compared to catheter-based angiography with or without clinical follow-up?
2. Are there patients, situations or setting where the results of CT angiography would preclude the use of catheter-based angiography without changing clinical outcomes?
3. What are the rates of revascularization procedures, hospitalizations and utilization of other diagnostic tests following CT angiography compared to catheter-based angiography?
4. What is the evidence for harms related to CT angiography compared to catheter-based angiography?

Methods

Search strategy

A full search of the MED clinical evidence core sources was done to identify systematic reviews (SRs), meta-analyses (MAs), technology assessments (TAs), and clinical practice guidelines (CPG) using the terms computed tomographic coronary angiography, CCTA, and diagnosis. Searches of core sources were limited to citations which were published after 2000. The core sources searched included: Hayes, Inc., ECRI, Cochrane Library (Wiley Interscience), UK National Institute for Health and Clinical Excellence (NICE), Blue Cross/Blue Shield Health Technology Assessment (HTA) program, Veterans Administration TA program, BMJ Clinical Evidence, the Canadian Agency for Drugs and Technologies in Health (CADTH), Washington State HTA, U.S. Services Preventive Task Force, and the Agency for Health Research and Quality (AHRQ).

A MEDLINE (Ovid) search was conducted to identify SRs and MAs as well as additional diagnostic test studies published after June 2009 since a good quality SR of 89 studies assessing the diagnostic test characteristics of CCTA (e.g., sensitivity, specificity) was published in 2010 (Schuetz 2010). The ending search date for the Schuetz (2010) SR was June 2009. However, we searched for controlled trials and observational studies that examined the impact of using CCTA on clinical outcomes (e.g., myocardial infarction, revascularization procedures) and further diagnostic testing (e.g., stress ECG, invasive coronary angiography), hospitalization following evaluation in the emergency room, cost, and harms from 2005 (the first published studies of scanners with 64 slices) through February 2010. Please see Appendix A for the full MEDLINE search strategy.

A search for relevant CPGs from 2005 through 2010 was also conducted, using the following sources: the National Guidelines Clearinghouse database, the Institute for Clinical Systems Improvement (ICSI), the Scottish Intercollegiate Guidelines Network (SIGN), the National Institute for Health and Clinical Excellence (NICE), the Veterans Administration/Department of Defense (VA/DOD) guidelines, American Heart Association, and the American College of Chest Physicians.

Inclusion criteria

Population: Adults with chest pain and suspected obstructive coronary artery disease

Intervention: Coronary computed tomographic angiography (CCTA)

Comparator: Catheter-based invasive coronary angiography (ICA)

Outcome: Diagnosis of obstructive coronary artery disease (greater than or equal to 50% stenosis), prognosis (including need for revascularization procedures, hospitalizations, coronary heart disease events), and harms (complications of the procedure, radiation dose, acute kidney injury, incidental findings).

Setting: Emergency department, inpatient and outpatient settings

Exclusion criteria

Studies were excluded if they published:

- in languages other than English;
- before January 2009 (for diagnostic test studies); or
- before January 2005 (for controlled trials and observational studies assessing outcomes including utilization, cost and harms).

Quality assessment

The methodological quality of the included studies was assessed using standard instruments developed and adapted by the MED Project that are modifications of the systems in use by NICE and SIGN (Guyatt 2008; NICE 2009; SIGN 2009). All studies and guidelines were assessed by two independent and experienced raters. In cases where there was not agreement about the quality of the study or guideline the disagreement was resolved by conference or the use of a third rater.

Each study was assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases. In brief, good quality SRs included a clearly focused question, a literature search that was sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., randomized controlled trials (RCTs)) and assess study quality, and assessments of heterogeneity to determine if a meta-analysis would be appropriate. Good quality RCTs clearly described the population, setting, intervention and comparison groups; randomly allocated patients to study groups; concealed allocation; had low dropout rates; and reported intention-to-treat analyses. Good quality SRs and RCTs also had low potential for bias

from conflicts of interest and funding source. Good quality diagnostic test studies prospectively studied consecutive patients who are representative of patients who will receive the test in practice, performed the test and the reference (gold) standard on all patients with the decision to perform the test and reference standard being independent of each other, and interpreted the results of the test and reference standard in a blinded fashion (without knowledge of the results of the other test). All good quality studies included *conflict of interest statements and descriptions of the source of funding and guarded* against undue influence of these factors. Fair quality SRs, RCTs and other diagnostic test studies had incomplete information about methods that might mask important limitations. Poor quality SRs, RCTs and diagnostic test studies had clear flaws that could introduce significant bias.

The overall strength or quality of the evidence was rated using a modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. After assessing the quality of individual studies a summary judgment of the overall quality of evidence was made for each key question and/or outcome (Guyatt 2008). The GRADE system defines the quality of a body of evidence for an outcome in the following manner:

- High: Further research is *very unlikely* to change our confidence in the estimate of effect. Typical sets of studies would be large RCTs without serious limitations.
- Moderate: Further research is *likely* to have an important impact on our confidence in the estimate of effect and may change the estimate. Typical sets of studies would be RCTs with some limitations or well-performed observational studies with additional strengths that guard against potential bias and have large estimates of effects.
- Low¹: Further research is *very likely* to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Typical sets of studies would be RCTs with very serious limitations or observational studies without special strengths.

The methodological quality of the guidelines was assessed using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration (AGREE 2009). Each guideline was assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases. A good guideline has fulfilled all or most of the criteria. A fair quality guideline will have fulfilled some of the criteria and those criteria not fulfilled are thought to unlikely alter the recommendations. If no or few of the criteria have been met, the guideline should be rated as poor. All guidelines were assessed by two independent and experienced raters. In cases where there was not agreement about the quality of the study or guideline the disagreement was resolved by conference or the use of a third rater.

Findings

Our MED Project core source search identified three SRs, 13 TAs, one RCT and five CPGs relevant to this topic. Because the Schuetz (2010) and Ollendorf (2010) SRs were good quality

¹ The MED Project collapses the low and very low GRADE categories because they usually have the same policy implications.

and included almost all of the diagnostic test studies included in prior SRs and TAs, we included only these two SRs. We also included the Washington State Health Care Authority Health Technology Assessment (HTA) (ICER 2008) because 1) it provided a good quality SR; 2) it focused on the clinical decision making related to the use of CCTA; and 3) it included studies of clinical outcomes, harms and costs. The MEDLINE search retrieved 747 full citations. After a review of citations and abstracts, we identified two additional diagnostic test studies (Hamirami 2010; Weustink 2010) and one RCT (Goldstein 2007) and four additional observational studies (Abidov 2009; Hadamitzky 2009; Karlsberg 2010; May 2009), not included in the SRs, that addressed clinical outcomes, harms or costs. A total of five guidelines were identified and used in this report. Detailed evidence tables by Key Question are presented in the appendices.

Key Question #1: What is the sensitivity and specificity of CT angiography in diagnosing obstructive coronary artery disease compared to catheter-based angiography with or without clinical follow-up?

Systematic reviews

Three recent good quality SRs with meta-analyses (ICER 2008; Ollendorf 2010; Schuetz 2010) examined the diagnostic accuracy of CCTA for the detection of CAD compared to ICA as a reference standard (Appendix B). Schuetz (2010) included 89 prospective studies using CT scanners of at least 12 detector rows (slices per scan cycle). *Their meta-analysis gave a pooled mean sensitivity of 97% (95% confidence interval [CI], 96%-98%), specificity of 87% (95% CI, 85%-90%), likelihood ratio (LR)² associated with a positive test result of 7.7 (95% CI, 6.2-9.5) and likelihood ratio associated with a negative test result of 0.03 (95% CI, 0.02-0.04).* They also found that scanners with at least 16 slices compared to scanners with fewer slices had a statistically significant increase in sensitivity (98% vs. 96%, respectively, $p < 0.05$) but not in specificity (90% vs. 85%, respectively, $p = 0.07$). A patient heart rate under 60 beats per minute was also associated with a statistically significant increase in sensitivity (99% vs. 96%, respectively, $p < 0.001$) but not specificity (86% vs. 87%, respectively, $p = 0.55$). Given the very high sensitivity (97%) and reasonably high specificity (87%), Schuetz (2010) concluded that CCTA can accurately detect and rule out CAD (stenosis greater than or equal to 50%) when compared to ICA, the current reference or gold standard.

It should be noted that the prevalence of CAD in the studies analyzed by Schuetz is quite high (59%) compared to the population who would likely get this test and may result in an overestimate of both sensitivity and specificity. Schuetz (2010) rated the articles for quality and determined them to be poor to fair in quality. Because so many of the patients in these studies had CAD, Schuetz (2010) noted these studies had a moderate to high risk of disease spectrum and verification bias. These biases would result in an overestimation of the sensitivity and specificity of CCTA.

² Likelihood ratio (LR) is the likelihood or odds that a given test result would occur in a patient *with the disease* compared to the likelihood that the same test result would occur in a patient *without the disease*. Likelihood ratios greater than 1.0 increase the probability of disease, and LRs less than 1.0 decrease the probability of disease. Likelihood ratios have a large impact on the probability of disease when they are greater than 10 or less than 0.1.

The SR by Ollendorf (2010) included a meta-analysis of 42 studies comparing the diagnostic accuracy of CCTA for 64-slice CT scanners to ICA. Ollendorf (2010) included fewer studies than Schuetz (2010) because Ollendorf (2010) restricted their SR to CT scanners with 64 slices or greater. Pooled sensitivity and specificity are similar to Schuetz (2010), sensitivity 98% (95% CI, 96%-99%) and specificity 85% (95% CI, 81%-89%).

The technology assessment performed by ICER (2008) for the Washington State Health Care Authority included a meta-analysis of 41 studies comparing 64-slice CCTA to ICA, the reference standard. Pooled sensitivity and specificity of CCTA for detection of CAD are similar to Schuetz (2010) and Ollendorf (2010), sensitivity 98% (95% CI, 97%-98%) and specificity 82% (95% CI, 80%-84%).

Diagnostic test studies (cross-sectional)

All studies identified since 2009 evaluated only 64-slice CT scanners. Two recent cross-sectional diagnostic test studies (Harnirani 2010; Weustink 2010) evaluated the diagnostic accuracy of 64-slice CCTA for the detection of CAD using ICA as a reference standard. Weustink (2010), a fair quality study, evaluated 517 consecutive patients referred for ICA in the Netherlands. Comparison of stress ECG and CCTA for diagnostic accuracy showed better sensitivity, specificity, positive likelihood ratio and negative likelihood ratio for CCTA compared to stress ECG in the overall group and in subgroups based on pre-test probability of CAD, defined as low (less than 20%) intermediate (20-80%) and high (greater than 80%). The overall sensitivity was 99% (95% CI, 97%-100%) and specificity 89% (95% CI, 84%-93%). Specificity varied from 72% (pre-test probability greater than 80%) to 93% (intermediate pre-test probability of 20%-80%) depending on the pre-test probability. In contrast, the sensitivity was stable across pre-test probabilities (99%-100%). The complete results are given in Appendix B.

Hamirami (2010) retrospectively reviewed 122 patients with intermediate to high pre-test probability of CAD who underwent CCTA and stress nuclear perfusion imaging (NPI) prior to ICA (Appendix B). For patients with coronary stenosis of more than 50%, CCTA had higher sensitivity and specificity than NPI (sensitivity, 99% vs. 56%, respectively; specificity, 74% vs. 39%, respectively).

Overall summary, quality and limitations of the evidence

There is consistency across studies of the diagnostic accuracy of CCTA compared to ICA for the detection of CAD. *The sensitivity is 97% or better and the specificity ranges from 72%-93%.* Coronary computed tomographic angiography may be better than stress ECG or NPI in diagnosing CAD.

The studies are all cross-sectional and employ convenience samples using patients already scheduled for ICA. This method of sampling patients creates a bias toward enrolling patients with a higher prevalence of CAD (mean prevalence 59%) than that expected in patients likely to get CCTA. Many patients who are likely to get a CCTA are in emergency room or primary care settings and would have a lower probability of CAD, versus a 59% probability or prevalence of CAD. Estimates of the sensitivity and specificity of CCTA from these studies may be higher than estimates from samples of patients who would get the test, creating a spectrum bias or effect.

Although many of the studies were poor to fair quality, the overall quality of the evidence is moderate because of the consistency of the results across the studies. However, the estimates of sensitivity and specificity should be viewed as the upper bound of sensitivity and specificity due to spectrum bias (from higher prevalence of CAD in the studies compared to the prevalence in patients who might typically get CCTA).

Key Question #2: Are there patients, situations or settings where the results of CT angiography would preclude the use of catheter-based angiography without changing clinical outcomes?

Systematic reviews

The Washington State Health Technology Assessment (ICER 2008) evaluated studies that assessed the impact of CCTA on patient outcomes (Appendix C). ICER (2008) identified seven studies that address patient outcomes, all coming from the ED setting. The evidence for this Key Question is based on one fair quality RCT (Goldstein 2007) and six poor quality case series (Hoffmann 2006; Hollander 2007; Johnson 2007; Pundziute 2007; Rubenshtein 2007; Savino 2006). Goldstein (2007) randomly assigned 197 patients without known CAD seen in the ED for chest pain to CCTA or usual care. All patients had normal ECGs and cardiac enzymes, so were at very low to low risk for myocardial infarction. Of the 99 patients randomized to the CCTA care arm, 67 (68%) patients with normal CCTA were discharged home rapidly per protocol. Twenty-four (24%) patients with indeterminate or non-diagnostic CCTA had stress NPI, and 8 (8%) patients with severe CAD on CCTA had ICA. The 98 patients in the control arm had standard ED observation, serial cardiac enzymes and stress NPI. Of these, 93 (95%) had normal stress NPI and were discharged home. No patients in either arm of the study had adverse outcomes (i.e., death, myocardial infarction, unstable angina, or test complications) at six months follow-up. In this small study, there were savings of evaluation time and money due to earlier discharge of patients without evidence of CAD. Six poor quality case series also demonstrated that a negative CCTA allows discharge patients from the ED without adverse events (Hoffmann 2006; Hollander 2007; Johnson 2007; Pundziute 2007; Rubenshtein 2007; Savino 2006). ICER (2008) applied these data to 1000 hypothetical 55 year old men seen in the ED with chest pain and normal ECGs, and initial cardiac enzymes. *Out of 1000 patients, early CCTA would result in 456 patients being discharged early, a reduction of false negative diagnoses for CAD from 51 to 5, a reduction in ICAs from 464 to 380 and a reduction of negative ICAs from 246 to 116 (ICER 2008).*

The Washington HTA cautions that the studies are all small and that the rate of acute coronary syndrome (ACS) and cardiac events were quite low; this low prevalence could make the strategy of early discharge seem better than it would in a patient setting with higher risk of CAD and ACS.

The Ollendorf (2010) SR included one RCT (Goldstein 2007) and six case series from ED settings and four case series from outpatient settings (Appendix C); all but three of the case series (Danciu 2007; Hay 2009; Wagdi 2009) were included in the ICER (2008) report. The seven ED studies found that early triage of low risk patients with CCTA resulted in no adverse cardiac events and was time saving compared to standard ED care. Four case series of CCTA for low risk patients with chest pain in the outpatient setting found no adverse cardiac events over 12

to 19 months of clinical follow-up. Ollendorf (2010) found serious methodological flaws in almost all of the studies evaluated.

RCTs

The only fair quality RCT (Goldstein 2007) was included in the two reviews above.

Other study designs

We found one good quality prospective cohort study and two poor quality cohort or case series studies not included in the Washington HTA (ICER 2008) or Ollendorf SR (2010) (Appendix C).

Hadamitzky (2009), a good quality cohort study, prospectively followed 1150 patients referred for CCTA in Germany. Of 802 (70%) patients without CAD on CCTA, there were four major adverse cardiac events (MACEs) (0.5%) and one non-cardiac death (0.1%). For 348 (30%) patients with CAD on CCTA, there were 17 cardiac events (5%) and six non-cardiac deaths (2%). In this study, findings on CCTA predicted the subsequent occurrences of MACE and non-cardiac deaths with statistical significance ($p < 0.001$ and $p = 0.004$, respectively).

May (2009), a poor quality case series, compared length of stay and total expense for 53 consecutive ED patients with chest pain and low probability of CAD. Three patient groups were compared: standard care with observation and serial enzyme determinations, CCTA with further observation and CCTA with discharge if the CCTA was negative for CAD. Length of stay in the ED was reduced from 25 hours for standard care to 14 hours for CCTA and observation to 5 hours for CCTA with discharge ($p < 0.001$ between standard care and CCTA with discharge). Total costs were reduced from \$7600 for standard care to \$6100 for CCTA with observation to \$4250 for CCTA with discharge ($p < 0.001$ between standard care and CCTA with discharge). No adverse cardiac events were reported in any of the groups on follow-up at six months.

Abidov (2009), a poor quality case series, prospectively followed 199 patients referred for CCTA after a non-diagnostic NPI study. For the 93 patients that did not have CAD on CCTA, there were no cases of subsequent ICA or MACE after two years of follow-up. Of the 36 patients with 70% coronary stenosis, there were 24 (67%) subsequent ICAs and 12 MACEs.

Overall summary, quality, strengths and limitations of the evidence

The ICER (2008) and Ollendorf (2010) SRs included the only good quality RCT. In addition a number of retrospective and prospective cohort studies and case series have examined the rate of MACE, ICA or percutaneous coronary interventions (PCI) on follow-up of six months to three years. *The results are consistent both in the ED and in the outpatient setting that with a low to intermediate pre-test probability of CAD, a negative CCTA result is reliable in predicting the absence of subsequent cardiac events.* Although many of the observational studies are poor to fair quality, the overall quality of the evidence is moderate based on data from one fair quality RCT, one large good quality cohort study (Hadamitzky 2009), and the consistency of results across all studies.

Key Question #3: What are the rates of revascularization procedures, hospitalizations and utilization of other diagnostic tests following CT angiography compared to catheter-based angiography?

We found no studies that assessed revascularization or hospitalization rates following CCTA compared to ICA.

Other study designs

One poor quality, before and after study addressed the utilization of additional diagnostic testing following introduction of CCTA into a single cardiology practice (Appendix D). Karlsberg (2010) looked at the utilization of stress ECG, stress NPI and ICA in a large university and community based cardiology practice in southern California for the two years prior and two years following the introduction of CCTA into their practice. Review of the overall demographics of the patient base and other measures of the practice suggests that there was no significant change in the characteristics of the practice or its patients during the four years of observation. After the introduction of CCTA, the number of stress ECGs did not change but the number of stress NPIs decreased by 19% compared to before CCTA ($p = 0.02$). The number of ICAs decreased by 47% ($p < 0.01$) and the yield of positive results on ICA (i.e., ICA results led to PCI) increased from 19% to 28% ($p < 0.001$). The results suggest that CCTA may decrease the use of other intermediate diagnostic tests (i.e., stress NPI) and improve the selection of patients for ICA.

Overall summary, strengths and limitations of the evidence

Low quality, limited evidence suggests that findings on CCTA may decrease the use of other diagnostic tests and ICA.

Key Question #4: What is the evidence for harms related to CT angiography compared to catheter-based angiography?

Systematic review

The Washington HTA (ICER 2008) addresses the issue of harms associated with CCTA including radiation dosage, risks of contrast agents and the detection of unrelated findings on CT scans (incidental findings). Washington HTA concluded that CCTA is safe. Reported rates of serious contrast reactions and contrast induced nephropathy have been very low; the type and amount of contrast used is identical to other common CT procedures including ICA.

The amount of radiation dose for CCTA is similar to a CT scan of the abdomen or an ICA. It is not possible to measure absorbed dose for any patient directly and the amount of radiation absorbed varies with patient size and body type. Radiation dose is usually estimated based on radiation phantom studies. Table 5, which is adapted from ICER (2008), shows relative amounts of radiation from various exposures.

Table 5: Relative Amounts of Radiation Exposure from Different Sources

Radiation exposure scenario	Approximate effective dose (mSv)	Approximate dose in chest x-ray equivalents
Chest x-ray	0.02	1

Radiation exposure scenario	Approximate effective dose (mSv)	Approximate dose in chest x-ray equivalents
Round trip airline flight Seattle to New York	0.06	3
Computed Tomography Head	2.0	100
Computed Tomography Abdomen	10.0	500
CCTA	8-14	400-700
CCTA with newer gating techniques	2-5	100-250
Invasive coronary angiography (ICA)	5-7	250-350
Nuclear perfusion imaging (NPI)	9-13	450-650

Of note, CCTA followed by NPI followed by ICA may result in up to 1700 chest x-ray equivalents of radiation dose. Using CCTA to replace NPI is a more reasonable strategy than adding it to NPI. Hopefully, replacing NPI with CCTA will decreased the use of ICA and result in less radiation exposure overall.

There are relative benefits and harms from the incidental findings noted on CT of the chest (findings in the chest obtained during a CCTA). Approximately 40 to 80% of patients undergoing CCTA will have a finding that is not related to the coronary arteries; five to twenty percent will have a finding deemed clinically important enough for further evaluation. Although some of the patients with these incidental findings will have been judged to have received some benefit, findings from the few studies that have examined this question suggest that the proportion of patients receiving some benefit is very low, while additional risks, anxieties and costs are generated by the additional investigations.

RCTs and other study designs

There are no other studies that address this Key Question.

Overall summary, strengths and limitations of the evidence

The evidence for this Key Question comes from the Washington HTA (ICER 2008). The evidence on contrast reactions, radiation dose and incidental findings is well established from epidemiologic and other studies.

Guidelines

Summary of Guidelines and Quality Assessment

Five guidelines address one or more of the Key Questions (Appendix E). One guideline from the *Scottish Intercollegiate Guidelines Network (SIGN) (2007)* addresses CCTA only peripherally. This guideline concludes that CCTA is effective in establishing a diagnosis of CAD when performed by trained and skilled teams.

The *American College of Radiology (ACR) Appropriateness Criteria* (ACR 2008, 2010a, 2010b) address the appropriateness of CCTA in several different clinical scenarios. These include chest pain suggestive of ACS, acute chest pain with low probability of CAD and chronic chest pain with high probability of CAD. The ACR guidelines point out that CCTA may be limited in patients with 1) heart rates more than 65 beats per minute; 2) arrhythmias; and 3) dense calcifications of the coronary arteries. The guidelines also comment that in patients with high probability of CAD, a negative CCTA may be a false negative. In these patients ICA may be more appropriate than CCTA.

A joint guideline from the *American College of Cardiology Foundation* and a number of other organizations (Taylor 2010) also gives appropriateness ratings for CCTA. Clinical scenarios for which CCTA is thought appropriate include 1) acute chest pain with suspicion of ACS and low to intermediate probability of CAD (ED setting); 2) non-acute symptoms possible representing ischemic equivalent but with normal, uninterpretable or non-diagnostic ECG; 3) risk assessment (screening) in asymptomatic patients without known CAD with known family history and low pre-test probability or with intermediate pre-test probability and no known family history; and 4) in patients with continued symptoms and a prior normal stress ECG. Of note, other guidelines do not recommend CCTA for asymptomatic patients (i.e., as a screening test).

The *American College of Cardiology Foundation* (Kramer 2007) also issued a statement of competence for physicians wishing to perform CCTA. This guidelines recommends that physicians who perform CCTA should have knowledge of CT hardware, competence in acquisition and interpretation techniques, knowledge of post-processing (including the use of computer work stations), knowledge in contrast reactions and their treatment, knowledge of radiation, and techniques to reduce radiation exposure. The guidelines recommend fellowship training and a minimum of 50 cases per year and 30 hours of CME training every three years.

Comparison of guidelines and evidence summary

The guidelines are poor to fair quality. All of the guidelines recommend the use of CCTA for evaluation of patients without known CAD who present with acute chest pain and have low to intermediate risk of CAD. This recommendation is consistent with the evidence in Key Questions 1 and 2.

Recommendations for use of CCTA in asymptomatic patients would result in a substantial proportion of patients having a false positive test result, based on the evidence of diagnostic accuracy of CCTA in Key Question 1. At a 15% pre-test probability or prevalence of obstructive CAD in an asymptomatic population, the post-test probability of CAD with a positive CCTA (assuming a sensitivity of 97% and specificity of 85%) would be 54% (Appendix F). Almost half (46%) of patients with a positive CCTA would have a false positive test resulting in further evaluation and/or treatment. Even with a 25% pre-test probability (prevalence) of CAD, a positive result on a CCTA would result in a post-test probability of 68%, and 32% of patients would have a false positive test result. Although we did not find studies that addressed screening asymptomatic patients, we did not specifically search for evidence for the use of CCTA as a screening test because it was beyond the scope of this report. The HTA by ICER

(2008) identified only one study of CCTA as a screening test in asymptomatic patients with diabetes. The anticipated completion date for this study is December 2011.

Summary

General conclusions

Coronary computed tomographic angiography is an intermediate diagnostic test used to increase (if the test is positive) or decrease (if the test is negative) the probability of CAD in patients presenting with chest pain. It is used as an intermediate diagnostic test similar to other intermediate tests such as stress ECG, stress NPI and stress ECHO. In contrast to the other intermediate tests, *CCTA provides anatomic information about the coronary arteries, but not functional information about the myocardium* (heart muscle function).

Patient and technical factors affect the use and quality of CCTA. These factors are reflected in study inclusion and exclusion criteria and in guideline recommendations. The factors relate to 1) choice of patients; 2) choice of CT scanner; and 3) competence of physicians performing the procedure. Patient conditions that *preclude* the performance of CCTA or *limit the quality* of CCTA include:

- Obesity;
- Inability to hold one's breath for at least 20 seconds;
- Cardiac arrhythmias and heart rates of greater than 60 beats per minute;
- Coronary artery calcifications creating artifacts that interfere with analysis; and
- Contrast allergy or renal insufficiency.

All recent studies evaluate 64-slice CT scanners, and most experts state that 64 slices is the current minimum number of slices needed to perform the study with acceptable spatial and temporal resolution. Finally, physicians performing CCTA should have additional training in all aspects of the procedure and a minimum of 50 cases per year is recommended to maintain competence in the procedure.

Coronary computed tomographic angiography has a very high sensitivity (98%) and moderate to moderately high specificity (72-93%) for the detection of coronary artery stenosis, based on moderate quality evidence. These performance characteristics support the use of CCTA to "rule out" obstructive CAD in emergency room patients with acute chest pain and normal ECGs and initial cardiac enzymes and in outpatients with stable chest pain. The major utility of CCTA in these settings is the ability to identify those patients with no CAD, so they can be safely discharged without additional work-up or concern for future cardiac events.

In patients with low to intermediate risk of CAD, CCTA appears to have better diagnostic accuracy than ECGs and NPI, based on low to moderate quality evidence. In the ED setting, use of CCTA may reduce the length of stay and total costs. This is substantiated by one small randomized controlled trial (n = 197) and 7 observational studies suggesting that emergency room patients with low to intermediate pre-test probability of CAD and who have a negative CCTA may be discharged quickly without concern for MACE. Finally, CCTA may reduce the

number of subsequent tests including stress NPI and ICA, based on a single poor quality before and after study.

Although two specialty-based guidelines find CCTA “appropriate” for patients with chest pain and high risk of CAD and for screening of high risk asymptomatic patients, other guidelines recommend against these uses. Few studies specifically address these uses and the pre-test probabilities of CAD in these patient groups would likely result in a high number of false negatives (in symptomatic patients at high risk of CAD) and false positives (in asymptomatic patients at low to intermediate risk of CAD). For example, screening 10,000 asymptomatic patients with a 20% prevalence of obstructive CAD with CCTA would result in 1960 patients with a true positive test result and almost as many (1200 patients) with a false positive test result (Appendix F). This would result in 1200 patients potentially receiving unnecessary testing (e.g., ICA) and treatment.

Limitations of the evidence

The evidence on diagnostic accuracy comes primarily from convenience samples of patients already scheduled for ICA, increasing the prevalence or pre-test probability of CAD in these samples. This may lead to an over-estimation of the sensitivity and specificity of CCTA than that which would be expected based in a more typical population of patients likely to get CCTA. The evidence on the effect of CCTA on subsequent cardiac diagnostic testing and on subsequent cardiac events is based on only one small fair quality RCT, one good quality cohort study, 12 poor to fair quality cohort or case series studies, and one before and after study.

Policy Considerations

This report reviews current Medicare, private payor and participating MED state policies regarding CCTA coverage. A total of 13 policies were reviewed with respect to six key elements identified in the evidence review:

1. Use of low to intermediate patient pre-test probability of CAD to determine coverage;
2. Other patient criteria (e.g., obesity, heart rate, ability to hold one’s breath);
3. Exclusion of coverage for patients with known coronary artery disease;
4. Exclusion of coverage for screening in asymptomatic patients;
5. Requirement to use a 64-slice scanner; and
6. Requirement regarding physician competence to perform CCTA.

The 13 policies include nine Medicare Local Coverage Determinations (LCDs) applicable to participating MED states, two private payor policies (Aetna, Cigna), and two state policies (Minnesota, Washington). In 2008, Medicare determined that it would not issue a national coverage determination with respect to CCTA and that coverage should be determined by local contractors (CMS 2008). We therefore focus our review on LCDs applicable to MED participating states, which comprise a total of nine current LCDs. In addition, this analysis focuses on policy criteria relevant to the use of CCTA for purposes of diagnosing CAD, and does not address CCTA coverage for other purposes.

Appendix G provides a table summarizing the analysis of the 13 policies according to the six elements above. Appendix H provides further detail regarding coverage criteria for each policy.

1. Patient Pre-test Probability of CAD Criteria

With respect to use of CCTA for diagnostic purposes, four of the 13 policies reviewed limit coverage of CCTA exclusively to patients with low or intermediate pre-test probabilities of CAD (Aetna, Cigna, Medicare LCD for WV, Washington). These policies support the use of CCTA as a test to “rule out” obstructive CAD in patients with low to intermediate pre-test probabilities of CAD, and are consistent with the evidence findings in this report. Use of CCTA for these purposes is most likely to occur in ED and primary care settings.

We also note that several of the Medicare LCDs contain confusing language with respect to the use of high patient pre-test probability criteria in order to discourage use of CCTA for screening purposes (Medicare LCD for AR and OK). We highlight this point as a general caution for states using Medicare LCDs as a basis or reference for developing state CCTA coverage criteria.

2. Other Patient Criteria

Five of the 13 policies reviewed identify other patient criteria for coverage of CCTA, such as allergies, heart rate and obesity. Aetna’s policy provides good example language and is consistent with the evidence findings of this report. Specifically, the policy states that CCTA is considered experimental and investigational for persons with any of the following contraindications to the procedure:

1. Body mass index (BMI) greater than 40;
2. Inability to image at desired heart rate (under 80 beats per minute), despite beta blocker administration;
3. Person with allergy or intolerance to iodinated contrast material;
4. Persons in atrial fibrillation or with other significant arrhythmia; or
5. Persons with extensive coronary calcification by plain film or with prior Angston score greater than 1700.

Four of the nine LCDs (AR (Part A and B), OK, WV) also contain patient criteria, although the language in several of these policies is unclear (AR, OK) and less comprehensive than the Aetna policy (WV).

3. Patients with Known Coronary Artery Disease

While none of the state or private payor policies cover CCTA for patients with known CAD, five of the nine LCDs reviewed cover CCTA for patients with known CAD, usually in patients who are recently post-stent or post-coronary artery bypass surgery and having recurrent symptoms. These five LCDs apply to coverage policies in four states (AL, AR, OK, WV). While this report does not review evidence in relation to use of CCTA in patients with known CAD, we include this coverage element in our analysis to acknowledge that several policies do not cover CCTA for patients with known CAD.

4. Screening in Asymptomatic Patients

All of the policies reviewed exclude coverage of CCTA for screening in asymptomatic patients.

5. Requirement of 64-Slice Scanner

Nine of the 13 policies reviewed require use of a minimum of 64-slice scanners. These include five of the nine LCDs (AK, MN, OR, WA, WV), both state policies (MN, WA), and both private payor policies (Aetna, Cigna) reviewed. One additional LCD recommends but does not require the use of 64-slice scanners (AL). The three policies that do not require 64-slice scanners are LCDs that apply to two states (AR, OK).

6. Physician Competence to Perform CCTA

All of the LCDs set forth expectations that CCTA tests are performed under the direct supervision of physicians who meet competency guidelines defined by the American College of Cardiology (ACC) and American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005). The state policies (MN, WV) and private payor policies (Aetna, Cigna) reviewed do not outline expectations of physician competence. Please see Appendix G for a summary analysis of each policy according to the six elements discussed above, and Appendix H for relevant coverage criteria excerpted from each policy.

Appendix A. Updated Search Strategy

- 1 exp Coronary Angiography/
- 2 exp Angiography/
- 3 exp Heart Diseases/di, ra [Diagnosis, Radiography]
- 4 exp Heart/
- 5 3 or 4
- 6 2 and 5
- 7 1 or 6
- 8 exp Tomography, X-Ray Computed/
- 9 7 and 8
- 10 exp "Sensitivity and Specificity"/
- 11 9 and 10
- 12 exp Catheterization/
- 13 11 and 12
- 14 Comparative Study/
- 15 9 and 12 and 14
- 16 13 or 15
(catheter\$ adj7 ((cat or ct or compute\$ or tomogra\$) adj3 scan\$)).mp. [mp=protocol
17 supplementary concept, rare disease supplementary concept, title, original title, abstract,
name of substance word, subject heading word, unique identifier]
- 18 5 and 17
- 19 16 or 18
- 20 exp coronary Angiography/ae, co, ct, mo [Adverse Effects, Complications, Contraindications,
Mortality]
- 21 exp Tomography, X-Ray Computed/ae, ct, mo [Adverse Effects, Contraindications, Mortality]
- 22 exp Catheterization/co, ct, mo [Complications, Contraindications, Mortality]
- 23 20 or 21 or 22
- 24 5 and 23
- 25 limit 24 to (english language and yr="2009 -Current")
- 26 exp Radiation Dosage/
- 27 1 or 3
- 28 26 and 27
- 29 ae.fs.
- 30 ct.fs.
- 31 29 or 30
- 32 28 and 31

33 exp treatment outcome/
34 exp Myocardial Revascularization/
35 9 and 33
36 9 and 34
37 exp Hospitalization/
38 9 and 37
39 35 or 36 or 38
40 limit 39 to yr="2009 -Current"
41 limit 40 to english language
42 limit 19 to (english language and yr="2009 -Current")
43 limit 32 to yr="2009 -Current"
44 25 or 41 or 42 or 43

Appendix B. Sensitivity, Specificity, and Likelihood Ratios³ for CT Angiography in Diagnosing Obstructive Coronary Artery Disease Compared to Catheter-Based Angiography with or without Clinical Follow-up

Reference Study Design and Number of Studies	Intervention(s); Comparator(s)	Outcomes Evaluated and Main Findings	Quality Rating* and Comments																														
Systematic Reviews and HTAs																																	
Schuetz (2010) SR and MA of 89 prospective diagnostic test studies	CCTA with CT scanners with at least 12 detector rows; >50% stenosis used as an abnormal finding for CAD. ICA used as a reference standard.	Pooled Diagnostic Accuracy Mean (95% CI): <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Sensitivity</th> <th style="text-align: center;">Specificity</th> <th style="text-align: center;">Positive Likelihood ratio (LR)</th> <th style="text-align: center;">Negative LR</th> </tr> </thead> <tbody> <tr> <td>Overall</td> <td style="text-align: center;">97% (96-98)</td> <td style="text-align: center;">87% (84-90)</td> <td style="text-align: center;">7.7 (6.2-9.5)</td> <td style="text-align: center;">0.03 (0.02-0.04)</td> </tr> <tr> <td>Suspect CAD</td> <td style="text-align: center;">98% (96-99)</td> <td style="text-align: center;">89% (86-92)</td> <td style="text-align: center;">9.1 (7.0-11.8)</td> <td style="text-align: center;">0.03 (0.02-0.04)</td> </tr> <tr> <td>Suspect ACS</td> <td style="text-align: center;">96% (87-98)</td> <td style="text-align: center;">77% (951-91)</td> <td style="text-align: center;">4.1 (2.0-8.4)</td> <td style="text-align: center;">0.06 (0.02-0.19)</td> </tr> <tr> <td>Heart rate < 60</td> <td style="text-align: center;">99% (98-99)</td> <td style="text-align: center;">86% (79-91)</td> <td></td> <td></td> </tr> <tr> <td>Heart rate > 60</td> <td style="text-align: center;">96% (95-97)</td> <td style="text-align: center;">88 (84-91)</td> <td></td> <td></td> </tr> </tbody> </table>		Sensitivity	Specificity	Positive Likelihood ratio (LR)	Negative LR	Overall	97% (96-98)	87% (84-90)	7.7 (6.2-9.5)	0.03 (0.02-0.04)	Suspect CAD	98% (96-99)	89% (86-92)	9.1 (7.0-11.8)	0.03 (0.02-0.04)	Suspect ACS	96% (87-98)	77% (951-91)	4.1 (2.0-8.4)	0.06 (0.02-0.19)	Heart rate < 60	99% (98-99)	86% (79-91)			Heart rate > 60	96% (95-97)	88 (84-91)			Good quality SR and MA. Quality of the 89 studies was rated as poor to moderate by SR authors
	Sensitivity	Specificity	Positive Likelihood ratio (LR)	Negative LR																													
Overall	97% (96-98)	87% (84-90)	7.7 (6.2-9.5)	0.03 (0.02-0.04)																													
Suspect CAD	98% (96-99)	89% (86-92)	9.1 (7.0-11.8)	0.03 (0.02-0.04)																													
Suspect ACS	96% (87-98)	77% (951-91)	4.1 (2.0-8.4)	0.06 (0.02-0.19)																													
Heart rate < 60	99% (98-99)	86% (79-91)																															
Heart rate > 60	96% (95-97)	88 (84-91)																															
Ollendorf (2010) SR and MA of 42 prospective diagnostic test studies	CCTA with CT scanners of 64 detector rows; 50% stenosis used as abnormal finding for CAD. ICA used as reference standard.	Pooled Diagnostic Accuracy Mean (95 % CI) <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Sensitivity</th> <th style="text-align: center;">Specificity</th> </tr> </thead> <tbody> <tr> <td>Overall</td> <td style="text-align: center;">98% (96-99%)</td> <td style="text-align: center;">85% (81-89%)</td> </tr> </tbody> </table>		Sensitivity	Specificity	Overall	98% (96-99%)	85% (81-89%)	Good quality SR and MA. Publication bias, spectrum bias, clinical review bias noted in included studies.																								
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ICER (2008) TA of 41 studies	CCTA compared to Stress NPI and Stress Echo; ICA as reference standard	Diagnostic accuracy of CCTA in outpatient setting Pooled sensitivity = 0.98 (95% CI 0.97 to 0.98) Pooled specificity = 0.82 (95% CI 0.80 to 0.84)	Good quality SR																														
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* Quality ratings for the systematic reviews and technology assessment are based on the MED rating instruments derived from SIGN and NICE: Good, fair, poor. The quality of the individual studies included in the technology assessment and systematic reviews are based on various systems used by the authors. Many of these systems were derived from the Cochrane Collaboration's rating methods for diagnostic test studies.

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Appendix C: Subgroups of Patients, Situations or Settings Where the Results of CCTA Would Preclude the Use of Catheter-based Angiography without Changing Clinical Outcomes.

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SR indicates systematic review; MA meta-analysis; HTA health technology assessment; RCT randomized controlled trial; ED emergency department; CCTA coronary computed tomographic angiography; CAD coronary artery disease; MACE major adverse cardiac events; ACS acute coronary syndrome (myocardial infarction or unstable angina); ICA invasive coronary angiography also catheter coronary angiography; MI myocardial infarction; NPI nuclear perfusion imaging; PCI percutaneous coronary intervention.

*Quality ratings for the systematic reviews and technology assessment are based on the MED rating instruments derived from SIGN and NICE: Good, fair, poor. The quality of the individual studies included in the technology assessment and systematic reviews are based on various systems used by the authors. Many of these systems were derived from the Cochrane Collaboration's rating methods for diagnostic test studies.

⁵ Odds Ratio = Odds Ratio = the ratio of two odds. An odds is the ratio of the probability of an event occurring versus the probability of the event not occurring (probability of event/[1-probability of event]) for a group. In this case, the odds of MACE in patients with CAD on CCTA are 17 times greater than the odds for patients with no CAD on CCTA.

Appendix D: Rates of Revascularization Procedures, Hospitalizations and Utilization of Other Diagnostic Tests Following CT Angiography Compared to Catheter-based Angiography.

Reference Study Design and number of studies	Intervention(s); Comparator(s)	Outcomes Evaluated and Main Findings	Quality Rating* and Comments																																																																								
Individual Studies																																																																											
Karlsberg (2010); chart review from one cardiology practice in California	CCTA	<p>Rates of utilization of stress ECG, stress NPI and ICA before and after introduction of CCTA:</p> <table border="1"> <thead> <tr> <th></th> <th>2004</th> <th>2005</th> <th>2006</th> <th>2007</th> <th>p value (2004 vs. 2007)</th> </tr> </thead> <tbody> <tr> <td colspan="6"><i>Practice demographics</i></td> </tr> <tr> <td>Office visits</td> <td>31,855</td> <td>29,617</td> <td>20,049</td> <td>30,066</td> <td>ns</td> </tr> <tr> <td>Hospital admissions/consults</td> <td>3,416</td> <td>2,878</td> <td>2,773</td> <td>3,468</td> <td>ns</td> </tr> <tr> <td colspan="6"><i>Non Invasive Procedures</i></td> </tr> <tr> <td>ECG</td> <td>15,679</td> <td>13,358</td> <td>13,309</td> <td>14,670</td> <td>ns</td> </tr> <tr> <td>SPECT</td> <td>3,223</td> <td>3,139</td> <td>2,810</td> <td>2,614</td> <td>0.021</td> </tr> <tr> <td>CCTA</td> <td>0</td> <td>74</td> <td>1,405</td> <td>945</td> <td>n/a</td> </tr> <tr> <td colspan="6"><i>Invasive Procedures</i></td> </tr> <tr> <td>ICA</td> <td>2,083</td> <td>1,848</td> <td>1,589</td> <td>1,150</td> <td>0.012</td> </tr> <tr> <td>PCI</td> <td>405</td> <td>457</td> <td>425</td> <td>326</td> <td>ns</td> </tr> <tr> <td>PCI/ICA</td> <td>19%</td> <td>25%</td> <td>27%</td> <td>28%</td> <td>0.008</td> </tr> </tbody> </table>		2004	2005	2006	2007	p value (2004 vs. 2007)	<i>Practice demographics</i>						Office visits	31,855	29,617	20,049	30,066	ns	Hospital admissions/consults	3,416	2,878	2,773	3,468	ns	<i>Non Invasive Procedures</i>						ECG	15,679	13,358	13,309	14,670	ns	SPECT	3,223	3,139	2,810	2,614	0.021	CCTA	0	74	1,405	945	n/a	<i>Invasive Procedures</i>						ICA	2,083	1,848	1,589	1,150	0.012	PCI	405	457	425	326	ns	PCI/ICA	19%	25%	27%	28%	0.008	Poor quality
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CCTA indicates coronary computed tomography angiography; ECG electrocardiogram; stress refers to tests that are performed after a period of exercise on a treadmill; NPI nuclear profusion imaging; ICA invasive coronary angiography also catheter coronary angiography; SPECT single proton emission computed tomography; PCI percutaneous coronary intervention; ns not statistically significant; n/a not available.

*Quality ratings for the systematic reviews and technology assessment are based on the MED rating instruments derived from SIGN and NICE: Good, fair, poor. The quality of the individual studies included in the technology assessment and systematic reviews are based on various systems used by the authors. Many of these systems were derived from the Cochrane Collaboration's rating methods for diagnostic test studies.

Appendix E. Summary of Guidelines

Recommending body, year published	Guideline(s)	Evidence base	Overall quality*
Scottish Intercollegiate Guideline Network, Management of Stable Angina (SIGN 2007)	This older guideline only addresses CCTA peripherally. It states that CCTA is effective in establishing a diagnosis of coronary heart disease when performed by trained and skilled teams.	Systematic Review	Good
American College of Radiology, Appropriateness Criteria Chest Pain Suggestive of Acute Coronary Syndrome (ACR 2010a)	This guideline rates CCTA as 6 on a scale of 1-9 ⁶ for patients with low to intermediate likelihood for CAD in the absence of cardiac enzyme or ischemic ST changes. It is a reasonable alternative to stress testing. It may be limited in patients with heart rates more than 65 beats/ minute, in patients with arrhythmias and in patients with calcium scores greater than 400-600 Agaston units.	Literature review, expert consensus	Fair
American College of Radiology, Appropriateness Criteria. Acute Chest Pain—Low Probability of CAD (ACR 2008)	This guideline rates CCTA as 7 on a scale of 1-9 for patients with acute chest pain and a low probability of CAD. CT of the chest may also detect other causes of chest pain.	Literature review, expert consensus	Fair
American College of Radiology, Appropriateness Criteria. Chronic chest pain with high probability of CAD (ACR, 2010b)	This guideline rates CCTA as 7 on a scale of 1-9 for patients with chronic chest pain and a high probability of CAD. It states that false negative studies may occur in the high risk group and negative studies may still require further diagnostic testing.	Literature review, expert consensus	Fair
ACCF/SCCT/ACR/AHA/ ASE/ASNC/SASCI/SCAI/ACMR, 2010 Appropriate Use Criteria for CCTA (Taylor 2010)	This guideline lists multiple clinical scenarios and rates CCTA as inappropriate, appropriate or uncertain for patients with pretest probabilities of CAD of low intermediate and high for each clinical scenario. The resulting table is quite complex. Clinical scenarios and pretest probabilities for which CCTA is thought to be appropriate include: <ol style="list-style-type: none"> 1. Acute chest pain with suspicion of ACS and low to intermediate pretest probability of CAD with normal, uninterpretable or non-diagnostic ECG; 2. Non-acute symptoms possibly representing ischemic equivalent with normal, uninterpretable or non-diagnostic ECG; 3. Detection of CAD/Risk Assessment in asymptomatic patients without known CAD with low pretest probability and known family history of 	Literature review, expert consensus	Fair

⁶ The American College of Radiology Appropriateness Criteria gives a numerical score for the appropriateness of any radiology test for a given clinical setting. The scale used is 1 to 9 with 1 being the least appropriate and 9 being the most appropriate. The rating score is determined by expert consensus without published endpoints for individual scores. The American College of Radiology does not assign ranges that it considers “inappropriate” or “appropriate” but the relative scores for a series imaging tests for any clinical symptom does give some indication of relative appropriateness.

Recommending body, year published	Guideline(s)	Evidence base	Overall quality*
	premature CAD; 4. Detection of CAD/Risk Assessment in asymptomatic patients without known CAD with intermediate pretest probability and no family history of CAD; and 5. Continued symptoms with prior normal ECG stress test.		
ACCF/AHA Clinical Competence Statement on Vascular Imaging With Computed Tomography and Magnetic Resonance (Kramer 2007)	This guideline lists competence criteria for providers who perform CCTA. These include: <ol style="list-style-type: none"> 1. Knowledge of advances in CT hardware; 2. Competence in acquisition and interpretation techniques; 3. Knowledge of post-processing technique; and 4. Knowledge of contrast reactions and their treatment and techniques to reduce radiation dosage. The guideline recommends fellowship training, a minimum of 50 cases per year and 30 hours of CME training every 3 years.	Literature review, expert consensus	Fair

* The methodological quality of the guidelines was assessed using an instrument adapted from the instrument developed by the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration

Appendix F. Number of Asymptomatic Patients with True Positive and False Positive Results on CT Angiography Based on Prevalence of CAD in a Population*

Pre-test probability of CAD (prevalence if disease in the population)	True positive test result (number of patients with a positive test result who have CAD)	False positive test result (number of patients with a positive test result who do not have CAD)	Post-test probability of CAD if the test result is "positive" (positive predictive value)
1%	98	1485	6%
5%	490	1425	26%
10%	980	1350	42%
15%	1470	1275	54%
20%	1960	1200	62%
25%	2450	1125	68%
50%	4900	750	87%
75%	7350	375	95%

* Calculations were based on sensitivity of 98% and specificity of 85% from the meta-analysis by Ollendorf (2011) and 10,000 patients in a population. (See calculations below.) The pre-test probability for a patient may be estimated using clinical information and the Duke or Framingham risk scores.

Calculations for Appendix F

Obstructive Coronary Artery Disease (1% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	98 (98%)	1485	1583 patients with a positive test result
Negative CCTA	2	8415 (85%)	8417 patients with a negative test result
Totals	100	9900	10,000 patients

Obstructive Coronary Artery Disease (5% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	490 (98%)	1425	1915 patients with a positive test result
Negative CCTA	10	8075 (85%)	8085 patients with a negative test result
Totals	500	9500	10,000 patients

Obstructive Coronary Artery Disease (10% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	980 (98%)	1350	
Negative CCTA	20	7650 (85%)	
Totals	1000	9000	10,000 patients

Obstructive Coronary Artery Disease (15% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	1470 (98%)	1275	
Negative CCTA	30	7225 (85%)	
Totals	1500	8500	10,000 patients

Obstructive Coronary Artery Disease (20% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	1960 (98%)	1200	
Negative CCTA	40	6800 (85%)	
Totals	2000	8000	10,000 patients

Obstructive Coronary Artery Disease (25% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	2450 (98%)	1125	3575 patients with a positive test result
Negative CCTA	50	6375 (85%)	6425 patients with a negative test result

Totals	2500	7500	10,000 patients
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Obstructive Coronary Artery Disease (50% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	4900 (98%)	750	5650 patients with a positive test result
Negative CCTA	100	4250 (85%)	4350 patients with a negative test result
Totals	5000	5000	10,000 patients

Obstructive Coronary Artery Disease (75% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	7350 (98%)	375	7725 patients with a positive test result
Negative CCTA	150	2125 (85%)	2275 patients with a negative test result
Totals	7500	2500	10,000 patients

Obstructive Coronary Artery Disease (90% prevalence)

Diagnostic test result	Present n (%)	Absent n (%)	
Positive CCTA	8820 (98%)	150	8970 patients with a positive test result
Negative CCTA	180	850 (85%)	1030 patients with a negative test result
Totals	9000	1000	10,000 patients

Appendix G. Analysis of Select Medicare, State and Private Payor CCTA Coverage Policies

LCD Number	State	Limits coverage to patients with low-intermediate pretest probability of CAD	Sets forth other patient criteria (e.g. obesity)	Covers for patient with known CAD	Covers Screening in asymptomatic patients	Requires 64 slice scanner	Sets forth physician competence expectations for performing procedure
L30047	Alabama (Part A+B)	No	No	Yes	No	Rec'd only	Yes
L24692	Alaska Oregon Washington Minnesota (Part A)	No	No	No	No	Yes	Yes
L23654	Alaska Oregon Washington (Part B)	No	No	No	No	Yes	Yes
L22038	Arkansas (Part B)	No	Yes	Yes	No	No	Yes
L24781	Arkansas (Part A)	No	Yes	Yes	No	No	Yes
L30288	Minnesota (Part B) Missouri (Part A+B)	No	No	No	No	Yes	Yes
L26751	Oklahoma (Part A+B)	No	Yes	Yes	No	No	Yes
L25907	West Virginia (Part A)	No	No	Yes	No	Yes	Yes
L22559	West Virginia (Part B)	Yes	Yes	No	No	Yes	Yes
AETNA	-	Yes (Low only)	Yes	No	No	Yes	No
CIGNA	-	Yes	No	No	No	Yes	No
MN DHS	Minnesota (state policy)	No	No	No	No	Yes	No
WA DSHS	Washington (state policy)	Yes	No	No	No	Yes	No

Appendix H. Select Medicare, State and Private Payor CCTA Coverage Policies

1. L30047 – Radiology: Computed Tomography Angiography of the Heart and Coronary Vessels (FI and C)

State/Region: Alabama

Contractor: Cahaba Government Benefit Administrators, LLC

Contractor Type: MAC – Part A

Effective Date: 05/04/2009 (original determination); 10/01/2010 (revisions)

Indications

As an alternative to invasive coronary angiography following a stress test that is equivocal or suspected to be inaccurate.

Instead of myocardial perfusion imaging in the evaluation of coronary artery disease in those patients who have moderate pre-test probability of disease based on clinical risk factors and abnormal diagnostic studies, not symptoms alone.

To evaluate the cause of symptoms in patients with known coronary artery disease.

Assessment of suspected congenital anomalies of coronary circulation or great vessels.

Assessment of coronary or pulmonary venous anatomy for the procedures described below:

- CTA of the coronary veins is indicated when imaging of the coronary venous anatomy is necessary for biventricular pacemaker lead insertion.
- CTA of the pulmonary veins is indicated when imaging of the pulmonary vasculature is necessary for pulmonary vein catheter ablation procedures for atrial fibrillation.

Limitations

Since the majority of the clinical research utilized a 64-slice CT scanner it is the recommended equipment. However, the intent of this LCD is not to monitor equipment utilization.

The procedure must be performed under the direct supervision of and interpreted by a cardiologist or radiologist who meets the competency guidelines outlined by the published guidelines, ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance, or American College of Radiology Clinical Statement on Noninvasive Cardiac Imaging.

NOT COVERED:

CPT 75571

Using 71275 or 76497

The procedure is not expected to be performed on an emergency department patient.

Screening tests are defined as those tests done in the absence of signs, symptoms, or presence of disease. The use of these procedures (75572, 75573, 75574 for coronary CT angiography) in patients without signs, symptoms or presence of disease is considered to be screening by this Contractor.

2. **L24692 – Multidetector Computed Tomography of the Heart and Great Vessels (FI)**

State/Region: Alaska, Oregon, Washington, and Minnesota

Contractor: Noridian Administrative Services, LLC

Contractor Type: FI

Effective Date: 06/01/2007 (original determination); 10/01/2010 (revisions)

Note: Providers should seek information related to National Coverage Determinations (NCD) and other Centers for Medicare & Medicaid Services (CMS) instructions in CMS Manuals. This LCD only pertains to the contractor's discretionary coverage related to this service.

This medical policy consolidates and replaces all previous policies and publications on this subject by Noridian Administrative Services (NAS) and its predecessors for Medicare A.

Multidetector Computed Tomography (MDCT) with its advanced spatial and temporal resolution has opened up new possibilities in the imaging of the heart, coronary arteries, and major vessels of the chest. The MDCT technology uses thin (up to 1 mm) slices, 0.5 to 0.75 mm reconstructions, multiple simultaneous images (e.g. 16 or more "slices") and cardiac gating (often requiring beta blockers for ideal heart rate). There is significant post processing, depending on the number of slices per second, for image generation. Coronary artery images show a high correlation both with stenotic lesions noted on diagnostic cardiac catheterization and with atheromas on intracoronary ultrasound. Current evidence demonstrates that computed tomographic coronary angiography (CTCA) can reliably rule out the presence of significant coronary artery disease (CAD) in a patient with a low to intermediate probability of having CAD and can reliably achieve the high degree of diagnostic accuracy necessary to avoid conventional angiography in selected patients with a negative study (high predictive value of a negative study).

Indications

The **only** covered indications are as follow.

1. CTCA is covered for the evaluation of patients with acute chest pain presenting in an emergency room (or equivalent) when necessary to rapidly differentiate among reasonably probable aortic, pulmonary and/or coronary etiologies.
2. CTCA is covered as first-line testing for CAD in patients with low to intermediate risk factors* presenting in an emergency room with chest pain or other symptoms strongly suggestive of coronary disease (or in another site with an equivalent acute presentation). Enzymes and EKGs must be normal or borderline and the provider believes a negative CTCA will avoid invasive coronary angiography.
3. CTCA is covered for the exclusion of CAD following an equivocal or discordant or suspected inaccurate stress (or stress imaging) test in patients with low to intermediate risk factors the provider believes a negative CTCA will avoid invasive coronary angiography.
4. CTCA is covered for the evaluation of patients in sinus rhythm scheduled to undergo non-coronary (e.g., valvular) cardiovascular surgery who are unlikely to have coronary artery disease and/or significantly calcified coronary arteries and the provider believes a negative CTCA will avoid invasive coronary angiography.
5. CTCA or MDCT of the heart and great vessels is covered to assess surgical eligibility or for preoperative planning, in patients who have clinical findings strongly suggestive of a congenital anomaly of the coronary vessels or great vessels.
6. MDCT of the heart is covered for evaluation of pulmonary veins and atrium in patients with atrial fibrillation and/or flutter when evaluation avoids what would otherwise be a medically reasonable and necessary MRI in patients who are scheduled to undergo ablation therapy evaluation.

*For the purposes of this policy, "intermediate risk" is defined as TIMI < 4 and/or other equivalent accepted national standard, i.e., a standard describing the same or comparable level of risk.

Limitations

1. These tests are never covered for screening. Ultrafast CT scan of the heart (electron-beam tomography [EBT] or electron-beam computed tomography [EBCT]) is **not** a covered service.
2. The value of MDCT or CTCA for “risk stratification” in patients or scenarios not described in the Indications section of this LCD has not been sufficiently established and this use is non-covered.
- 3 Demonstration and/or quantification of the presence of coronary calcification in either asymptomatic or symptomatic patients with or without signs of atherosclerotic heart disease have not been shown to improve outcomes and is not covered. Until such time as there may be more evidence of medical necessity, Medicare will not pay for the quantitative evaluation of coronary calcium by MDCT, CTCA, EBCT or other technology.
4. At the initiation of any of these procedures, there must be an initial scout radiograph or other imaging assessment of cardiac calcification. The physician must make an assessment of the anatomic location, degree and intensity of calcification, and impact of calcification on the utility of test results. The CTCA will be subject to denial when post-pay review indicates that calcification of the coronary segment(s) in question, or other likely causes of significant artifact, will lead to invasive angiography to establish diagnosis.
5. Both false positive findings and number of non-evaluable segments increase proportionately with coronary calcification and may cause conversion to or result in invasive coronary angiography. Therefore, in patients with an overall Agatston calcium score of 600 or greater, documentation must indicate the medical necessity of proceeding with the examination, rather than converting to invasive arteriography". (For example, the physician might note the absence of significant calcification in the area of interest to support continuing with this study but rather proceed to conventional arteriography.
6. The selection of the test should be made within the context of other testing modalities and the resulting information should be essential to the management decision, not merely an additional layer of testing.
7. The administration of beta blockers and/or other drugs necessary for the study, any cardiograms, rhythm strips, IV drugs and other supplies and the monitoring of the patient during MDCT by a physician experienced in the use of cardiovascular drugs are included herein and are not separately payable services.
8. All studies must be ordered by a physician or a qualified non-physician practitioner.
9. A physician must be present for direct supervision during testing. (This requirement is presumed to be met in the hospital outpatient department.)
10. Coverage of this modality for coronary artery assessment is limited to devices that process thin, high resolution slices. Less resolution and slower rotation speeds result in a higher number of nonevaluable segments. Based on current literature, Medicare requires the multidetector scanner to either have *both* collimation of 0.625 mm or less, and a rotational speed of 375 msec or less OR, alternatively, at least 64 slice detector design. Machines not meeting these requirements should not have studies submitted for payment.
11. Only one study, MDCTA of the heart and great vessels or chest CT, will be covered on a single date of service.
12. The MDCTA evaluation of both cardiac structure, morphology, and ventricular function in congenital heart disease (CPT 75573) remains non-covered by Medicare until such time as there is more evidence of the medical necessity for these procedures, including the specific clinical circumstances that describe both where and why these studies are needed for patient management]
13. Until such time as there is more evidence of the medical necessity for quantitative evaluation of coronary calcium, Medicare may not cover the procedure for coronary calcium scoring (75571).

Acceptable Levels of Competence for Performance and Interpretation

The acceptable levels of competence, as defined by the American College of Cardiology (ACC)/American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005), are outlined as follows:

"For the technical portion, a recommended level of competence is fulfilled when the image acquisition is obtained under all of the following conditions:

- a. The service is performed by a radiologic technologist who is credentialed by a nationally recognized credentialing body (American Registry of Radiologic Technologists or equivalent) and meets state licensure requirements where applicable.
- b. If intravenous beta blockers or nitrates are to be given prior to a CT coronary angiogram or calcium score, the test must be under the direct supervision of a certified registered nurse and physician (familiar with the administration of cardiac medications) who are available to respond to medical emergencies and it is strongly recommended that the certified register nurse and physician be ACLS certified.
- c. When contrast studies are performed, the physician must provide direct supervision and the radiologic technologist or registered nurse administering the contrast must have appropriate training on the use and administration of contrast media."

For the professional portion, a recommended level of competence is fulfilled when the interpretation is performed by a physician meeting the following requirements:

- "a. The physician has appropriate additional training in CT Coronary Angiography and cardiac CT imaging equivalent to the guidelines set forth by the ACC or ACR (for example: the ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the ACR Clinical Statement on Noninvasive Cardiac Imaging (2005)), or
- b. The physician has appropriate medical staff privileges to interpret CT Coronary Angiograms at a hospital that participates in the Medicare program, and is actively training in cardiac CT (as in paragraph a). A grace period of 24 months should be allowed to acquire the necessary training."

3. L23654 – Multidetector Computed Tomography of the Heart and Great Vessels (Carrier)

State/Region: Alaska, Oregon, Washington

Contractor: Noridian Administrative Services, LLC

Contractor Type: Carrier

Effective Date: 05/20/2007 (original determination); 10/01/2010 (revisions)

Coverage determination same as L24692.

4. **L22038 – Cardiac Computed Tomography (CCT) (Carrier)**

State/Region: Arkansas

Contractor: Pinnacle Business Solutions, Inc. - Arkansas

Contractor Type: Carrier

Effective Date: 02/15/2006 (original determination); 05/01/2010 (revisions)

A. Indications:

The Multi-detector Computed Tomography (MDCT) (cardiovascular computed tomography (CCT)) may be employed for the following:

1. Emergency evaluation of acute chest pain syndrome for coronary etiology, including emergency evaluation, pulmonary embolism, aortic dissection, and coronary artery disease;
2. Cardiac evaluation of a patient with chest pain syndrome (e.g., anginal equivalent, angina) who is not a candidate for cardiac catheterization;
3. Management of a symptomatic patient with known coronary artery disease (e.g., post-stent, post CABG) when the results of the MDCT may guide the decision for repeat invasive intervention;
4. Assessment of suspected congenital anomalies of coronary circulation or great vessels; and
5. Assessment of coronary veins prior to biventricular pacing lead placement.

B. Limitation

1. Coverage of CT coronary angiography is limited to CT devices that process thin (up to 1 mm) slice, 0.5 to 0.75 mm reconstruction, and multiple simultaneous images.
2. The selection of the test should be made within the context of other testing modalities so that the resulting information facilitates the management decision, not merely adds a new layer of testing. Patient selection should be made with a high pretest probability of disease and must not be used for screening. This includes:
 - Patients with irregular heart rhythm.
 - Patients who have difficult breath hold, which of course will be much better with the 64 slice CT.
 - Patients with extreme morbid obesity will be a limitation.
 - Patients with serious intravenous iodinated contrast allergies.
 - Patients with renal insufficiency for fear of contrast induced nephropathy.
 - Heavily calcified coronary arteries would be a limiting factor for exact determination of diameter stenosis.
 - Patients with acute coronary syndrome with chest pain and S-ST segment changes should go directly for invasive coronary angiogram.
 - Radiation exposure should be considered as one of the limiting factors.
3. Electron Beam CT (EBCT) is not covered for use in coronary artery examination (Applicable to 75571 in which calcium scoring is done.)
4. The patient's treating physician or qualified non-physician practitioner must order the study.
5. Studies must be conducted under the direct supervision of a cardiologist and/or radiologist. IV beta blockers may be administered by a qualified non-physician practitioner as long as the direct supervision requirements are met.
6. All studies must be done by staff trained and accredited to do Computed Tomography. The supervising and interpreting physician must have appropriate additional training in CT Coronary Angiography and cardiac CT

imaging, equivalent to the guidelines set forth by the ACC (for cardiologists) and ACR (for radiologists), as found in the ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance and the ACR Clinical Statement on Noninvasive Cardiac Imaging. A team approach for reading cardiac and non-cardiac computed tomography of the chest is suggested. This team-based approach assures that the beneficiary receives the newest in technology in the most competent hands. Once accreditation guidelines are in place, policy will be revised accordingly.

5. **L24781 – Cardiac Computed Tomography (CCT) (FI)**

State/Region: Arkansas

Contractor: Pinnacle Business Solutions, Inc. - Arkansas

Contractor Type: FI

Effective Date: 08/01/2006 (original determination); 05/01/2010 (revisions)

Coverage determination same as L22038.

6. **L30288 – Computed Coronary Tomography Angiography (Carrier)**

State/Region: Minnesota Part B, Wisconsin, Missouri Part A & B

Contractor: Wisconsin Physicians Service Insurance Corporation

Contractor Type: Carrier

Effective Date: 08/16/2009 (original determination); 02/21/2011 (revisions)

Multi-slice or Multi-detector Computed Tomography (MDCT) with its advanced spatial and temporal resolution has opened up new possibilities in the imaging of the heart and major vessels of the chest, including the coronary arteries.

The MDCT technology requires thin (up to 1mm) slices, 0.5 to 0.75 mm reconstructions, multiple simultaneous images (e.g. 16, 32, 64 or more slices) and cardiac gating (often requiring beta blockers for ideal heart rate).

The current available body of evidence appears to demonstrate that coronary CTA (CCTA) can reliably rule out the presence of significant coronary artery disease (CAD) in patient with a low to intermediate probability of having CAD and can reliably achieve a high degree of diagnostic accuracy necessary to replace conventional angiography in selected situations

In some circumstances, CCTA may be proposed instead of, or in addition to, other noninvasive cardiac tests. This is particularly useful in the commonly encountered clinical scenario of patients having an equivocal stress myocardial perfusion test. The information from CCTA may be used to guide further diagnostic evaluation and/or appropriate therapy (e.g., revascularization versus medical management) and this may over the long term influence the morbidity from CAD.

It is expected that the levels of competence for both the technical and professional components of the procedure will be in compliance with those guidelines defined by the American College of Cardiology (ACC) American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005).

Indications

1. Coronary CTA used as an alternative to invasive angiography, following a stress test that is equivocal or suspected to be inaccurate.

Coronary CTA might be used as a triage tool as an alternative to invasive coronary angiography in select patients who have an equivocal or suspected inaccurate stress (or stress imaging) test. The rationale is that a noninvasive coronary anatomic test (CCTA) might permit a separate method of assessing the coronary arteries which is different from a stress test and limit the number of normal invasive coronary angiograms. It could also help avoid missing serious coronary disease in those suspected of having an inaccurate stress test result.

2. Coronary CTA for suspected congenital anomalies of the coronary circulation.

Coronary CTA is used to assess patients suspected of having a congenital coronary anomaly. The cross-sectional nature of this technique allows one to definitively determine both the presence and possible future harm that could result from the anomaly. It is often used after an anomaly has been suspected following a different test such as prior invasive coronary angiogram. A coronary CTA is used to decide if surgery is indicated and for surgical planning.

3. Coronary CTA for evaluation of acute chest pain in the emergency department (ED).

The rationale for the application of coronary CTA in this setting is to quickly triage patients in order to rule out coronary artery disease as a possible cause of symptoms. It is hoped that the application of coronary CTA in the emergency room would limit resource use in chest pain patients who do not have coronary artery disease. It is preferable that CCTA in the ED be ordered by a cardiologist.

4. CTA for the assessment of coronary or pulmonary venous anatomy

This application of CTA for the coronary and pulmonary veins is primarily for pre-surgical planning. Coronary venous anatomy can be useful for the cardiologist who needs to place a pacemaker lead in the lateral coronary vein in order to resynchronize cardiac contraction in patients with heart failure. This may be helpful to guide biventricular pacemaker placement.

Pulmonary vein anatomy can vary from patient to patient. Pulmonary vein catheter ablation can isolate electrical activity from the pulmonary veins and allow for the elimination of recurrent atrial fibrillation. The presence of a pulmonary venous anatomic map may help eliminate procedural complications and allow for the successful completion of the procedure.

Limitations

1. The test is never covered for screening, i.e., in the absence of signs, symptoms or disease.
2. The selection of the test should be made within the context of other testing modalities such as stress myocardial perfusion images or cardiac ultrasound result so that the resulting information facilitates the management decision, not merely adds a new layer of testing.
3. The test may be denied, on post-pay review, as not medically necessary when used for cardiac evaluation of a patient where there is a pre-test knowledge of sufficiently extensive calcification of the coronary segment in question that would diminish the interpretive value.
4. Coverage of this modality for coronary artery assessment is limited to devices that process thin, high resolution slices (1 mm or less). The multidetector scanner must have at least 64 slices per rotation capability.
5. The administration of beta blockers and the monitoring of the patient during CCTA by a physician experienced in the use of cardiovascular drugs are included and are not separately payable services.
6. All studies must be ordered by a physician or a qualified non-physician practitioner similar to any other medical testing such as the stress myocardial perfusion imaging or ultrasound evaluation.
7. For contrast enhanced examinations a physician must be present for direct supervision during testing similar to the stress myocardial perfusion imaging.
8. The electron beam tomography (EBT) technology or Ultrafast CT is not covered by this LCD for coronary artery examination.
9. Atrial fibrillation by itself is not an indication; atrial fibrillation with planned ablation therapy is allowed.

7. **L26751 – Cardiac Computed Tomography (CCT) (MAC – Part A)**

State/Region: Oklahoma Part A & B

Contractor: TrailBlazer Health Enterprises, LLC

Contractor Type: MAC – Part A

Effective Date: 03/31/2008 (original determination); 01/01/2011 (revisions)

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered.

Indications:

The Multi-Detector Computed Tomography (MDCT) (Cardiovascular Computed Tomography (CCT)) may be employed for the following:

- Emergency evaluation of acute chest pain syndrome for coronary etiology, including emergency evaluation, pulmonary embolism, aortic dissection and coronary artery disease.
- Cardiac evaluation of a patient with chest pain syndrome (e.g., anginal equivalent, angina) who is not a candidate for cardiac catheterization.
- Management of a symptomatic patient with known coronary artery disease (e.g., post-stent, post-CABG) when the results of the MDCT may guide the decision for repeat invasive intervention.
- Assessment of suspected congenital anomalies of coronary circulation or great vessels.
- Assessment of coronary veins prior to biventricular pacing lead placement.

Limitations:

Coverage of CT coronary angiography is limited to CT devices that process thin (up to 1 mm) slice, 0.5 to 0.75 mm reconstruction, and multiple simultaneous images.

The selection of the test should be made within the context of other testing modalities so that the resulting information facilitates the management decision, not merely adds a new layer of testing. Patient selection should be made with a high pretest probability of disease and must not be used for screening. This includes:

- Patients with irregular heart rhythm.
- Patients who have difficult breath hold, which of course will be much better with the 64-slice CT.
- Patients with extreme morbid obesity will be a limitation.
- Patients with serious intravenous iodinated contrast allergies.
- Patients with renal insufficiency for fear of contrast-induced nephropathy.
- Heavily calcified coronary arteries would be a limiting factor for exact determination of diameter stenosis.
- Patients with acute coronary syndrome with chest pain and S-ST segment changes should go directly for invasive coronary angiogram.
- Radiation exposure should be considered as one of the limiting factors.

Electron Beam CT (EBCT) is not covered for use in coronary artery examination.

The patient's treating physician or qualified non-physician practitioner must order the study.

Studies must be conducted under the direct supervision of a cardiologist and/or radiologist. IV beta blockers may be administered by a qualified non-physician practitioner as long as the direct supervision requirements are met.

All studies must be done by staff trained and accredited to perform computed tomography.

The supervising and interpreting physician must have appropriate additional training in CT coronary angiography and cardiac CT imaging, equivalent to the guidelines set forth by the ACC (for cardiologists) and ACR (for radiologists), as found in the ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance and the ACR Clinical Statement on Non-Invasive Cardiac Imaging.

The CPT Category III Cardiac Computed Tomography Angiography (CCTA) codes include thorough review and reporting on all of the CT source images acquired. Per the ACR guidelines, non-cardiac structures imaged at the time of cardiac imaging must be reviewed and reported for pathology in addition to the cardiac structures. Medicare expects that when the CPT Category III CCTA codes are reported, all of the work described by the codes will have been performed. Although a physician may elect to have a separate physician interpret a portion of the images (e.g., non-cardiac structure images interpreted by a radiologist and cardiac structures interpreted by a cardiologist) only one professional component per study may be reported to Medicare regardless of the number of physicians contributing to the overall interpretation.

8. **L25907 - Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (FI)**

State/Region: Virginia, West Virginia

Contractor: National Government Services, Inc.

Contractor Type: FI

Effective Date: 12/01/2007 (original determination); 01/01/2011 (revisions)

Abstract:

The multidetector helical computed tomography (MDCT) technology requires thin (up to 1 mm) slices, 0.5 to 0.75 mm reconstructions, multiple simultaneous images (e.g. 16, 32, 64 or more slices), and cardiac gating (often requiring beta blockers for ideal heart rate). There is significant post-processing, depending on the number of slices per second for image generation. For coronary artery imaging, the resulting images show a high correlation with stenotic lesions noted on diagnostic cardiac catheterization but more importantly, with atheromas on intracoronary ultrasound.

Current available body of evidence demonstrates that CCTA can reliably rule out the presence of significant coronary artery disease (CAD) in patients with a low to intermediate probability of having CAD and can reliably achieve a high degree of diagnostic accuracy and technical performance necessary to replace conventional angiography.

Indications:

Patient presenting with chest pain syndrome. CCTA may be used in lieu of an imaging stress test. The clinician must have a high degree of suspicion that CAD is high on the differential diagnosis of the symptoms.

To facilitate the management decision of a patient with an equivocal stress test. CCTA might be chosen in select patients who have an equivocal stress (or stress imaging) test. The rationale is that a noninvasive coronary anatomic test (CCTA) allows an alternate method of assessing the coronary arteries, which would limit the number of negative invasive coronary angiograms.

When the recurrence of symptoms in patients with known coronary artery disease may be related to progression/exacerbation of underlying disease. The use of CCTA in this setting would be to evaluate the extent of previously diagnosed coronary artery disease. Patients with known disease may have had remote invasive angiography and/or stress testing to evaluate prior events or symptoms. New or recurrent symptoms may relate to a change in the coronary anatomy that can be assessed with CCTA.

When patients with prior bypass surgery or intracoronary artery stent placement present with chest pain or dyspnea. Coronary bypass grafts are relatively well seen with CCTA. The rationale for CCTA would be to determine the patency and severity of possible graft stenoses that may be the source of chest pain. Patients with prior intracoronary stents often present with recurrent chest pain. The rationale for a CCTA as an alternative to invasive angiography is to rule out in-stent restenosis as the cause of symptoms. (Accurate assessment of in-stent restenosis may be limited by the artifact caused by the stent material itself and the quality of the scan and scanner).

Suspected congenital anomalies of the coronary circulation. CTA is used to assess patients suspected of having a congenital coronary anomaly. The cross-sectional nature of this technique allows one to determine accurately both the presence and possible future harm that could result from the anomaly. It is often used after an anomaly has been identified following a different test such as prior invasive coronary angiogram. A CCTA is used to decide if surgery is indicated and for surgical planning.

The assessment of coronary or pulmonary venous anatomy. This application of CTA for the coronary and pulmonary veins is primarily for pre-surgical planning. Coronary venous anatomy can be useful for the cardiologist who needs to place a pacemaker lead in the lateral coronary vein in order to resynchronize cardiac contraction in patients with heart failure. This may be helpful to guide biventricular pacemaker placement. Pulmonary vein anatomy can vary from patient to patient. Pulmonary vein catheter ablation can isolate electrical activity from the pulmonary veins and allow for the elimination of recurrent atrial fibrillation. The presence of a pulmonary venous

anatomic map may help eliminate procedural complications and allow for the successful completion of the procedure.

The patient undergoing non-coronary artery cardiac surgery. Certain patients who have non-coronary artery cardiac surgery (valve or ascending aortic surgery) may need a pre-operative invasive coronary angiogram. The surgical planning may also depend upon the exact location of the coronary arteries. The rationale for the use of CCTA in these patient subsets is to avoid potentially unnecessary invasive testing and still provide appropriate pre-surgical information.

The test may be medically necessary in patients presenting to the emergency room with complaints consistent with cardiac ischemia, but without diagnostic electrocardiography (ECG) or enzymes.

The test may be considered medically necessary in patients status post revascularization procedures who present with recurrent symptoms not clearly identifiable as ischemic.

Limitations:

The test is never covered for screening, i.e., in the absence of signs, symptoms or disease.

The test will be considered not medically necessary if the anticipated results are not expected to provide new, additional information to that already previously obtained from other tests (such as stress myocardial perfusion images or cardiac ultrasound). New or additional information should facilitate the management decision, not merely add a new layer of testing.

For dates of service prior to 01/01/2010, determination of cardiac ejection fraction (CPT code 0151T) should not be billed when previously determined by other techniques. CPT code 0151T is deleted effective 12/31/2009.

The test will be considered not medically necessary if it is anticipated that the patient would require invasive cardiac angiography for further diagnosis or for therapeutic intervention. (e.g., angina decubitus, unstable angina, Prinzmetal angina, etc.)

The test may be denied, on post-pay review, as not medically necessary when used for cardiac evaluation if there were pre-test knowledge of sufficiently extensive calcification of the suspect coronary segment that would diminish the interpretive value.

Effective 12/01/2009, coverage for evaluation of coronary artery or bypass graft stenosis, or for functional status (e.g., wall motion), is limited to multidetector scanners having at least 64 slices per rotation capability. This two year period (12/01/2007 - 12/01/2009 will allow for a phase-in of new technology.

The administration of beta blockers and the monitoring of the patient during MDCT/CCTA by a physician experienced in the use of cardiovascular drugs is included as part of the test and is not a separately payable service.

All studies must be ordered by the physician/qualified non-physician practitioner treating the patient and who will use the results of the test in the management of the patient.

The test must be performed under the direct supervision of a physician.

This LCD does not address electron beam tomography (EBT) technology or Ultrafast CT for coronary artery examination. There is no extension of coverage of EBT based on this policy.

Quantitative calcium scoring (CPT code 0144T for dates of service prior to 01/01/2010, and CPT 75571 on or after 01/01/2010) is not a covered service and will be denied as not medically necessary. Calcium scoring reported in isolation is considered a screening service. When performed in association with CT angiography, there is neither separate nor additional included reimbursement for the calcium scoring.

Acceptable Levels of Competence for Performance and Interpretation: Providers submitting claims for these tests must demonstrate proficiency and training in performing the tests according to the following standards:

The acceptable levels of competence, as defined by the American College of Cardiology (ACC)/American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005), are outlined as follows:

For the technical portion, a recommended level of competence is fulfilled when the image acquisition is obtained under all of the following conditions:

The service is performed by a radiology technologist who is credentialed by a nationally recognized credentialing body (American Registry of Radiologic Technologists or equivalent) and meets state licensure requirements where applicable.

If intravenous beta blockers or nitrates are to be given prior to a CT coronary angiogram, the test must be under the direct supervision of a certified registered nurse and physician (familiar with the administration of cardiac medications) who are available to respond to medical emergencies and it is strongly recommended that the certified register nurse and physician be ACLS certified.

When contrast studies are performed, the physician must provide direct supervision and the radiologic technologist or registered nurse administering the contrast must have appropriate training on the use and administration of contrast media.

For the professional portion, a recommended level of competence is fulfilled when the interpretation is performed by a physician meeting the following requirements:

The physician has appropriate additional training in coronary CTA and cardiac CT imaging equivalent to the guidelines set forth by the ACC or ACR (for example: the ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the ACR Clinical Statement on Noninvasive Cardiac Imaging (2005)), or

The physician has appropriate medical staff privileges to interpret CT coronary angiograms at a hospital that participates in the Medicare program, and is actively training in cardiac CT (as in paragraph a). A grace period of 24 months will be allowed to acquire the necessary training.

9. **L22559 – Cardiac Computed Tomography & Angiography (CCTA) (Carrier)**

State/Region: West Virginia

Contractor: Palmetto GBA

Contractor Type: Carrier

Effective Date: 10/01/2006 (original determination); 10/01/2010 (revisions)

Indications and Limitations of Coverage

Cardiac computed tomographic angiography (CCTA), also known as computed tomography of the heart and coronary arteries, or multidetector computed cardiac tomography (MDCT) is considered reasonable and necessary for the evaluation of suspected symptomatic coronary artery disease (CAD) and for the detection of structural and morphologic intra- and extra-cardiac conditions.

Use of a CCTA is expected to avoid diagnostic cardiac catheterization. If high pre-test probability of CAD exists, Palmetto expects the patient to undergo invasive coronary angiography with appropriate percutaneous coronary intervention.

To establish CCTA medical necessity, your case must meet at least one indication in the following two categories:

Symptomatic Coronary Artery Disease (CAD)

1. Evaluation of Acute Chest Pain, unexplained dyspnea or symptoms suggesting angina pectoris (such as jaw pain) when there is:

- Intermediate pre-test probability of CAD*, **and**
- No EKG changes to suggest acute myocardial injury or ischemia, **and**
- Normal initial cardiac markers.

2. Evaluation of Chest Pain Syndrome, when there is:

- Intermediate pre-test probability of CAD*, **and**
- Uninterpretable EKG** **or** patient is unable to exercise, **or**
- Uninterpretable **or** equivocal stress test (exercise, perfusion **or** stress echo)

*Intermediate pretest probability of CAD by age, gender and symptoms is between 10 and 90% as referenced in the ACCF/ACR 2006 Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging.

** Uninterpretable EKG refers to EKGs with resting ST segment depression greater than or equal to 0.10mV, complete left bundle branch block, pre-excitation, or paced rhythm.

3. Evaluation of intracardiac structures for suspected coronary anomalies.

Suspected Cardiac Structural/Morphologic Anomalies

1. Detection of intracardiac and extracardiac structures in:

- Evaluation of cardiac mass (suspected tumor or thrombus) **or**
- Evaluation of pericardial conditions (mass, constrictive pericarditis, **or** complications of cardiac surgery), **or**
- Patients with technically limited images from echocardiogram, MRI **or** TEE.

2. Detection of morphologic intracardiac and extracardiac structures for:

- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation. While data is limited for 3D reconstruction of the left atrium for ablations, there is broad consensus among cardiologists that these images, which are integrated and used in real-time in the procedure room to shorten procedure time, improve therapeutic success and enhance patient safety, **or**
- Non-invasive coronary vein mapping prior to placement of biventricular pacemaker, **or**
- Non-invasive coronary arterial mapping, including internal mammary artery, prior to repeat cardiac

- surgical revascularization, **or**
- Detection of complex congenital heart disease including anomalies of coronary circulation, great vessels, and cardiac chamber and valves, **or**
- Evaluation of coronary arteries in patients with new onset heart failure to assess etiology.

Limitations:

1. Coverage of CCTA is limited to CT devices that process thin, high resolution slices. Decreased resolution and slower rotation speeds result in a higher number of non-evaluable segments. At the current time, Medicare requires the multidetector scanner to have collimation of 0.625 mm or less, and a rotational speed of 375 msec or less, OR to have at least 64 slice detector design. Do not submit studies from scanners that do not meet these requirements.
2. Medicare does **not** cover a screening CCTA for asymptomatic patients, risk stratification or quantitative evaluation of coronary calcium.

Ultrafast CT scan of the heart (electron-beam tomography [EBT] or electron-beam computed tomography [EBCT]) is **not** a covered service.

3. Simultaneous exclusion of obstructive CAD, pulmonary embolism, and aortic dissection (“triple rule-out”) in the emergency department is **not** covered. In order to optimize imaging of the RCA, contrast must be cleared from the right sided chambers during acquisition, a process that leads to suboptimal contrast timing in the pulmonary arteries. Simultaneous rule-out of aortic pathology (at the low pitch needed to properly image the coronaries) mandates thicker slices in order to capture the total volume required in a reasonable breath hold. The increased slice thickness degrades coronary image quality.
4. For CCTA patients must be able to lie still, follow breathing instructions, take nitroglycerine for coronary dilatation and take a beta-blocker or calcium blocker to achieve heart rates less than 70 BPM.
5. Prior to the initiation of a CCTA, there must be an imaging assessment of coronary calcification (calcium scoring). The physician must make an assessment of the anatomic location, degree and intensity of calcification and impact of calcification on the utility of the test results. CCTAs performed on patients with elevated quantitative calcium scores that preclude accurate assessment of coronary anatomy are **not** covered by Medicare.

Palmetto GBA expects that CCTA is performed under the direct supervision of a physician with appropriate training in CT coronary angiography and cardiac CT imaging equivalent to guidelines set forth by the ACC or ACR (Circulation 2005;112:598-617/ J Am Coll Cardiol. 2005;46:383-402)

10. **Aetna Policy – Clinical Policy Bulletin: Cardiac CT, Coronary CT Angiography and Calcium Scoring**

State/Region: n/a

Contractor: n/a

Contractor Type: n/a

Effective Date: 04/09/1998 (original determination); 12/07/2010 (revisions)

1. Aetna considers cardiac computed tomography (CT) angiography of the coronary arteries using 64 slices or greater medically necessary for the following indications:
 - A. Rule out significant coronary stenosis in persons with a low or very low pre-test probability of coronary artery disease by Framingham risk scoring or by American College of Cardiology criteria (see appendix), with any of the following indications:
 - a. Evaluation of persons with chest pain who cannot perform or have contraindications to exercise and pharmacologic stress testing (see appendix); *or*
 - b. Evaluation of persons with a positive (i.e., greater than or equal to 1 mm ST segment depression) exercise stress test; *or*
 - c. Evaluation of persons with chest pain presenting to the emergency department when an imaging stress test or coronary angiography are being deferred as the initial imaging study.
 - B. Evaluation of asymptomatic persons at low pretest probability of coronary heart disease by Framingham risk scoring (see appendix) who have an equivocal exercise or pharmacological stress test. **Note:** Current guidelines from the American Heart Association recommend against routine stress testing for screening asymptomatic adults.
 - C. Preoperative assessment of persons scheduled to undergo "high-risk" noncardiac surgery, where an imaging stress test or invasive coronary angiography is being deferred unless absolutely necessary. The American College of Cardiology defines high-risk surgery as emergent operations, especially in the elderly, aortic and other major vascular surgeries, peripheral vascular surgeries, and anticipated prolonged surgical procedures with large fluid shifts and/or blood loss involving the abdomen and thorax.
 - D. Preoperative assessment for planned noncoronary cardiac surgeries including valvular heart disease, congenital heart disease, and pericardial disease, in lieu of cardiac catheterization as the initial imaging study.
 - E. Detection and delineation of suspected coronary anomalies in young persons (less than 30 years of age) with suggestive symptoms (e.g., angina, syncope, arrhythmia, and exertional dyspnea without other known etiology of these symptoms in children and adults; dyspnea, tachypnea, wheezing, periods of pallor, irritability (episodic crying), diaphoresis, poor feeding and failure to thrive in infants).
2. Aetna considers CT angiography of cardiac morphology for pulmonary vein mapping medically necessary for the following indications:
 - A. Evaluation of persons needing biventricular pacemakers to accurately identify the coronary veins for lead placement.
 - B. Evaluation of the pulmonary veins in persons undergoing pulmonary vein isolation procedures for atrial fibrillation (pre- and post-ablation procedure).
3. Aetna considers cardiac CT for evaluating cardiac structure and morphology in congenital heart disease medically necessary for the following indications:
 - A. Anomalous pulmonary venous drainage;
 - B. Evaluation of other complex congenital heart diseases;
 - C. Evaluation of sinus venosum atrial-septal defect;
 - D. Kawasaki's disease;

- E. Person scheduled or being evaluated for surgical repair of tetralogy of Fallot or other congenital heart disease;
 - F. Pulmonary outflow tract obstruction;
 - G. Suspected or known Marfan's syndrome.
4. Aetna considers cardiac CT angiography experimental and investigational for persons with 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), despite beta blocker administration.
 - C. Person with allergy or intolerance to iodinated contrast material
 - D. Persons in atrial fibrillation or with other significant arrhythmia.
 - E. Persons with extensive coronary calcification by plain film or with prior Angston score greater than 1700.
5. Aetna considers coronary CT angiography experimental and investigational for screening of asymptomatic persons, evaluation of persons at intermediate or high pretest probability of coronary artery disease, evaluation of stent occlusion or in-stent restenosis, evaluation of persons with an equivocal PET rubidium study, and for all other indications.

Aetna considers cardiac CT angiography using less than 64-slice scanners experimental and investigational.

6. Aetna considers calcium scoring medically necessary for diagnostic cardiac CT angiography to assess whether an adequate image of the coronary arteries can be obtained.

Aetna considers calcium scoring (e.g., with ultrafast (electron beam) CT, spiral (helical) CT, and multi-slice CT) experimental and investigational for all other indications because the definitive value of calcium scoring for assessing coronary heart disease risk has not been established in the peer-reviewed published medical literature.

11. **CIGNA – Medical Coverage Policy: Computed Tomography Angiography (CTA)**

State/Region: all plans administered by CIGNA Companies, including plans administered by Great-West Healthcare

Contractor: n/a

Contractor Type: n/a

Effective Date: 08/15/2010 (original determination); 08/15/2011 (next review date)

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

- evaluation of chest pain in an individual with a very low, low, or intermediate pre-test probability of coronary artery disease¹ (CAD) when the individual cannot perform or has a contraindication to exercise and chemical stress testing (i.e. exercise treadmill stress test, stress echo, and nuclear stress test [i.e., myocardial perfusion imaging])
- exclusion of CAD in an individual with a low or very low pre-test probability of CAD when recent stress test results (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are uninterpretable, equivocal, or there is a suspicion that the results are falsely positive
- exclusion of CAD in an individual with an intermediate pre-test probability of CAD when recent stress test results (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are uninterpretable or equivocal, AND CTA will be performed in lieu of an angiography.
- exclusion of CAD in a symptomatic individual (e.g., acute chest pain in an emergency department setting), and the individual has an intermediate pre-test probability of CAD, and there are no changes noted on the ECG and serial enzymes are negative
- evaluation of suspected or known coronary artery anomalies associated with congenital conditions
- for morphologic evaluation of the coronary arteries in an individual with dilated cardiomyopathy or new onset heart failure, when ischemia is the suspected etiology and cardiac catheterization and/or nuclear stress test (i.e., myocardial perfusion imaging) have not been performed
- pre-operative assessment of coronary arteries in an individual undergoing repair of aortic dissection, aortic aneurysm repair or valvular surgery AND CTA will be performed in lieu of an angiography
- post-coronary artery bypass grafting (CABG) when BOTH of the following criteria are met:
 - repeat intervention is being considered
 - recent coronary angiography has been completed but additional information is needed before a treatment decision can be made

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

- evaluation of chest pain in an intermediate or high pre-test probability of CAD individual when recent stress test result (i.e., exercise treadmill, stress echo, or nuclear stress test [i.e., myocardial perfusion imaging]) are either clearly positive or unequivocally negative
- screening for CAD in an asymptomatic individual
- post-revascularization procedure (e.g., percutaneous coronary intervention, coronary artery bypass grafting surgery), including evaluation of bypass grafts, coronary anatomy or evaluation for in-stent restenosis except when an individual is post-coronary artery bypass grafting (CABG), repeat intervention is being considered but additional information is required following completion of recent coronary angiography.

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

12. Minnesota DHS – Authorization Criteria: Computed Tomography of Coronary Arteries

State/Region: Minnesota

Contractor: n/a

Contractor Type: n/a

Effective Date: 08/01/2010

MHCP will cover CT of cardiac coronary arteries when following are met.

Coverage Indications:

1. Coronary CTA requested as an alternative to invasive angiography, following a stress test that is equivocal or suspected to be inaccurate.
2. Coronary CTA for suspected congenital anomalies of the coronary circulation.
3. Coronary CTA for evaluation of acute chest pain in the emergency department (ED).
4. CTA requested for the assessment of coronary or pulmonary venous anatomy for pre-surgical planning

Contraindication/noncoverage:

1. The test is never covered for screening, i.e., in the absence of signs, symptoms or disease.
2. The selection of the test should be made within the context of other testing modalities such as stress myocardial perfusion images or cardiac ultrasound result so that the resulting information facilitates the management decision, not merely adds a new layer of testing.
3. Coverage of this modality for coronary artery assessment is limited to devices that process thin, high resolution slices (1 mm or less). The multidetector scanner must have at least 64 slices per rotation capability.
4. The administration of beta blockers and the monitoring of the patient during CCTA by a physician experienced in the use of cardiovascular drugs are included and are not separately payable services.
5. All studies must be ordered by a physician or a qualified non-physician practitioner similar to any other medical testing such as the stress myocardial perfusion imaging or ultrasound evaluation.
6. For contrast enhanced examinations a physician must be present for direct supervision during testing similar to the stress myocardial perfusion imaging.
7. The electron beam tomography (EBT) technology or Ultrafast CT is not covered for coronary artery examination.
8. Atrial fibrillation by itself is not an indication; atrial fibrillation with planned ablation therapy is allowed

13. **Washington State Health Care Authority – Health Technology Clinical Committee Findings and Coverage**

Decisions: Coronary Computed Tomography Angiography

State/Region: Washington

Contractor: n/a

Contractor Type: n/a

Effective Date: 05/08/2009 (original determination)

HTCC Coverage Determination

Coronary Computed Tomographic Angiography (CCTA) is **covered benefits with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination

Limitations of Coverage

- 1) Patients with low to intermediate risk of coronary artery disease;
- 2) For investigation of acute chest pain in an emergency department or hospital setting; and
- 3) Using Computed Tomography machines with 64-slice or better capability.

Non-Covered Indicators

- Patients who are asymptomatic or at high risk of coronary artery disease;
- CCTA used for coronary artery disease investigation outside of the emergency department or hospital setting; and
- CT scanners that use lower than 64- slice technology.

Appendix I. Relevant Codes

CODES	DESCRIPTION
ICD 9	
786.5	Chest pain
786.50	Chest pain unspecified
786.59	Discomfort, pressure, tightness in chest
413	Angina pectoris
414.0	Coronary atherosclerosis
CPT	
75574	Coronary computed tomographic angiography (CCTA)
78451-4	Nuclear perfusion imaging
93350	Stress echocardiography
93015	Stress ECG
93454	Cather coronary angiography (ICA)

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