Medical Policy

Subject:	Coronary Artery Imaging: Contrast-Enhanced Coronary Computed Tomography Angiography (CCTA) and Coronary Magnetic Resonance Angiography (MRA)
Policy #:	RAD.00035
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Description/Scope

This document addresses contrast-enhanced computed tomography angiography (CTA) of the coronary arteries (coronary CTA or CCTA) and magnetic resonance angiography (MRA) of the coronary arteries.

Note: This document does not address the use of electron beam computed tomography (EBCT) to quantify coronary calcification, which is addressed in RAD.00001 *Computed Tomography to Detect Coronary Artery Calcification*.

For further information regarding the use of CTA/MRA imaging for additional indications, refer to:

- CG-RAD-09 CTA/MRA of Thorax Cavity, Abdomen, Pelvis and Extremities

Position Statement

Medically Necessary:

Contrast-enhanced coronary computed tomography angiography (CCTA) or coronary magnetic resonance angiography (MRA) is considered **medically necessary** for the evaluation of suspected anomalous coronary arteries when conventional angiography has been unsuccessful or has provided equivocal results and the results could impact treatment.

Investigational and Not Medically Necessary:

Coronary computed tomography angiography (CCTA) or coronary magnetic resonance angiography (MRA) is considered **investigational and not medically necessary** for all other indications, including, but not limited to, the following:

- Screening for coronary artery disease (CAD), either in asymptomatic individuals or as part of a preoperative evaluation;
- Diagnosis of CAD, in individuals with acute or non-acute symptoms, or after a coronary intervention;
- As a technique to evaluate cardiac function.

Rationale

Coronary CT Angiography

Coronary CT Angiography (CCTA) to Detect Coronary Artery Disease (CAD)
Over the past several years, a large number of studies have addressed the diagnostic accuracy of coronary CT angiography (CCTA) in the evaluation of coronary artery disease (CAD). Studies can be broadly subdivided into those that address the use of CCTA in individuals with acute symptoms suggestive of CAD, and in individuals considered at intermediate risk for coronary artery disease, based either on symptoms, risk factors, or equivocal results of other cardiac imaging procedures, such as myocardial perfusion imaging (MPI) or echocardiography. In the setting of acute symptoms, CCTA has frequently been assessed as an emergency room triage technique to rapidly rule myocardial infarction either in or out. In the setting of non-acute symptoms, CCTA has been investigated primarily as a technique to determine candidacy for a subsequent invasive coronary angiography. Specifically, if a CCTA is considered normal, then an individual may forgo a coronary angiogram. Early studies of CCTA reported results from 16 row detectors and reported diagnostic outcomes according to the number of vessels or segments visualized. More recent literature has focused on 64 row detectors, which have greater spatial resolution, and have also reported diagnostic outcomes in terms of the individual patient. This latter analysis has been considered more appropriate than per vessel or segment analysis, since treatment decisions are made on a per-patient basis. It should also be noted that the majority of studies enrolled patients who were scheduled to undergo invasive coronary angiography for a variety of reasons. Therefore, invasive angiography represented the comparator gold standard imaging technique.

This large volume of studies was reviewed as part of a scientific statement published by the American Heart Association Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention (Bluemke, 2008). This review noted that the presence of hemodynamically relevant coronary artery stenoses in patients without bypass grafts or stents may be ruled out by CCTA with a high negative predictive value, ranging from 98-100% in most studies. This high negative predictive value of CCTA forms the basis for the assertion that CCTA may be useful to identify patients who would not benefit from coronary angiography. In contrast, the positive predictive value of CCTA may not be clinically relevant in patients at high risk for CAD based on symptoms, risk factors or other imaging techniques. These patients would most likely benefit from invasive angiography, since the likelihood is high that interventional treatment at the time of angiography would be necessary. Data regarding CCTA detection of restenosis in patients with coronary bypass grafts or intracoronary stents is more limited.

A 2008 study by Miller and colleagues is reviewed as a representative study of the diagnostic performance of CCTA (Miller, 2008). This multicenter study enrolled 291 patients with suspected CAD who underwent CCTA prior to a scheduled invasive coronary angiogram. The specific indications for the coronary angiogram or results of other imaging procedures (i.e., echocardiography or myocardial perfusion imaging) were not provided. The primary outcome was the accuracy of CCTA in detecting stenoses of 50% or more compared to the gold standard of invasive coronary angiography, based on a per-patient analysis. Accuracy was measured as the area under the receiver operating curve (AUC). The following statistics were reported:

Statistic	CCTA (95% confidence interval)
Accuracy (AUC)	0.93 (CI: 0.90-0.96)
Sensitivity	85% (CI:79-90)
Specificity	90% (CI:83-94)
Positive predictive value	91% (CI:86-95)
Negative predictive value	83% (75-89)

The authors concluded that an AUC of 0.93 indicates that CCTA using a 64 row detector has powerful discriminative ability among symptomatic patients to identify those with and without CAD. However, the negative predictive value of 83% is lower than other reports (Cademartini, 2007; Hausleiter, 2007; Haussman, 2008; Schlosser, 2007), and the authors state that, on this basis, CCTA cannot replace invasive coronary artery angiography in this population of symptomatic patients. The lower negative predictive value in this well controlled multi-center study is important to consider, particularly since a high negative predictive value forms the scientific rationale for the proposed clinical utility of CCTA to deselect patients for invasive coronary angiography. The authors hypothesize that the higher negative predictive value in other studies may be related to the limitations inherent in single-center designs and the degree of rigor used in controlling for bias in smaller studies. Heterogeneity in study results has also been noted in a 2006 meta-analysis by Hamon and colleagues. Miller and colleagues conclude by stating, "Further studies are needed to define [CCTA's] precise role in the diagnostic algorithm for the evaluation of patients with suspected coronary artery disease."

This last statement by the authors highlights a crucial point in the consideration of CCTA as a technique to diagnose CAD. Specifically, the diagnostic accuracy essentially represents an intermediate outcome. The final health outcome is related to how CCTA can be integrated into the overall management of the patient, considering both patient risk factors and the role of other established imaging methods, such as myocardial perfusion imaging or echocardiography. Both of these well established imaging techniques assess the functional significance of any stenosis, as opposed to the anatomy of the stenosis, as imaged by CCTA. While many studies have hypothesized that CCTA can be used to deselect patients for invasive angiography, this hypothesis has not been assessed in controlled trials or in registry reports. It is not clear what the final health outcome is for patients with an intermediate risk of CAD who have negative results from CCTA. For example, registry reports can provide important information regarding whether these patients undergo angiography. Randomized trials could compare the efficacy of CCTA vs. myocardial perfusion imaging as the initial study in patients with suspected CAD. Efficacy could be measured by a variety of cardiac outcomes assessed over medium and long term follow up.

Diagnostic accuracy is sometimes considered an adequate intermediate surrogate outcome in situations where there are limited other diagnostic techniques, or there are significant limitations in the gold standard. However, this is not the case for the evaluation of CAD where there are multiple other diagnostic techniques. Another consideration is the safety of CCTA. In the trial by Miller, the mean effective dose of radiation was 14mSv for men and 15 mSv for women, which exceeds that of coronary angiography. Even assuming a more conservative estimate of 8 mSv for a CCTA, the radiation dose is still 400 times the radiation dose of one chest x-ray. This radiation dose places CT scans at an intermediate (1–10 mSv) to moderate (10 mSv) level of risk under international guidelines, a risk level for which the corresponding benefit should be "moderate" to "substantial." Einstein and colleagues (2007) reported that their "Simulation models suggest that use of 64-slice CTCA is associated with a non-negligible LAR (lifetime attributable risk) of cancer" and that the risk is "Considerably greater for women, younger patients and for combined cardiac and aortic scans." Like coronary angiography, CTA also presents the risk of renal damage from the use of nephrotoxic contrast agents and of complications from the use of medicines to slow the heart rate to obtain a usable image. In addition, depending on how CCTA is integrated into cardiac work-up, the patient could be exposed to multiple different imaging tests with cumulative radiation exposure, particularly if CCTA results in an additional layer of imaging.

The need for final health outcomes to define the role of CCTA in the hierarchy of imaging tests is highlighted by an editorial accompanying the Miller study which noted:

Some proponents argue that diagnostic cardiac CT angiography should not be held to the same outcome standard as therapeutic procedures, since diagnostic procedures are not directly responsible for improved outcomes. However, the value of diagnostic tests lies in whether, by leading to a more appropriate choice of therapy, they ultimately result in better outcomes … Although [the Miller study] was carefully done and provides more data on diagnostic accuracy, it does not advance our knowledge of the appropriate use and possible benefits of the technology… Because all patients received both cardiac CT angiography and conventional coronary angiography and no data on outcomes are reported, the study does not answer this important question (Redberg, 2008).

The ACCURACY Trial (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) evaluated CCTA results from 230 of 245 individuals experiencing typical or atypical chest pain but without known CAD. This prospective study evaluated subjects with chest pain at 16 sites who were clinically referred for invasive coronary angiography (ICA). CCTAs were scored by consensus of three independent blinded readers. The ICAs were evaluated for coronary stenosis based on quantitative coronary angiography (QCA). A total of 230 subjects underwent both CCTA and ICA (59.1% male; mean age: 57 +/- 10 years). On a patient-based model, the sensitivity, specificity, and positive and negative predictive values to detect > or =50% or > or =70% stenosis were 95%, 83%, 64%, and 99%, respectively, and 94%, 83%, 48%, 99%, respectively. No differences in sensitivity and specificity were noted for non-obese compared with obese subjects or for heart rates < or =65 beats/min compared with >65 beats/min, whereas calcium scores >400 reduced specificity significantly. Pretest disease probability, radiation dose, incidental noncardiac finding prevalence and follow-up were not reported (Budoff, 2008b).

Additional studies and meta-analyses of 64-slice scanning have examined the diagnostic accuracy of CCTA in comparison to conventional ICA (Meijer, 2008; Mowatt, 2008a; Stein, 2008). In these and other prior studies of CCTA vs. ICA, high disease prevalence has a positive impact on the accuracy of the CCTA test results. The test accuracy of CCTA amongst patient populations with lower disease prevalence is of interest in the further assessment of clinical utility for CCTA in comparison to ICA results. In addition, the lack of health outcomes data that go beyond reports of diagnostic accuracy are the basis of the position statement identifying CCTA as an investigational technique to diagnose coronary artery disease.

Other organizations consider diagnostic accuracy an outcome adequate to support the routine use of CCTA in the evaluation of CAD. As noted above, in 2008 the American Heart Association Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention published a scientific statement on CCTA to evaluate CAD (Bluemke, 2008). Based on their literature review, the statement offered recommendations categorized according to the following criteria, based on class or recommendation and level of evidence. As noted, Class II recommendations include both the weight of evidence and opinion.

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
- Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful (Budoff, 2006).

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

The specific recommendation regarding CCTA for diagnosis of CAD is as follows:

- The potential benefit of noninvasive coronary angiography is likely to be greatest and is reasonable for symptomatic patients who are at intermediate risk for coronary artery disease after initial risk stratification, including patients with equivocal stress tests (Class IIa, level of evidence B).

In 2006, the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group published appropriateness criteria for cardiac computed tomography and cardiac magnetic resonance imaging (Hendel, 2006). This report took a consensus approach rather than purely evidence-based approach to develop the appropriateness criteria. Appropriateness criteria ranging from 0 to 9 were assigned to different clinical situations, where a score of 7-9 indicated an appropriate test, 4 to 6 indicated uncertainty regarding the specific indication, and a score of 1 to 3 identified an inappropriate test. Appropriateness scores for similar clinical indications have been developed for myocardial perfusion imaging (MPI) (Douglas, 2006). The following table summarizes the appropriate indications for CCTA and MPI for the diagnosis of CAD.

Indication	**Appropriateness Score CCTA**	**Appropriateness Score MPI**
Evaluation of chest pain syndrome in patient with intermediate pre-test probably of CAD or uninterpretable ECG or unable to exercise	7	7
Acute chest pain syndrome in patients with intermediate pre test probably of CAD or no EKG changes and serial enzymes negative	7	9
Evaluation of chest pain syndrome when there is an uninterpretable or equivocal stress test	8	N/A

Interpretation of the appropriateness scores is limited due to their consensus basis, but it is interesting to note that a myocardial perfusion scan is considered as appropriate or more appropriate than CCTA in the evaluation of a chest pain syndrome.

Summary
A variety of studies and meta-analyses have reported that CCTA has a high negative predictive value for CAD, and that CCTA is a potentially useful technique to deselect patients for invasive coronary artery angiogram, particularly those patients considered to be at intermediate risk of CAD. These studies, and resultant clinical recommendations and appropriateness criteria, have focused on the diagnostic accuracy of CCTA. In contrast, there are inadequate data to support the clinical utility of CCTA, specifically how CCTA will be integrated into the management of patients with suspected CAD, and how CCTA will ultimately improve patient outcomes. These final health outcomes are considered important, due to multiple other imaging and evaluation options. In addition, CCTA is associated with significant radiation exposure, which is a concern given that some patients may undergo multiple imaging tests. Therefore, the lack of health outcomes data that go beyond reports of diagnostic accuracy are the basis of the position statement identifying CCTA as an investigational technique to diagnose coronary artery disease.

Coronary CT Angiography to Evaluate Anomalous Coronary Arteries
Anomalous coronary arteries are an uncommon finding at angiography, occurring in ~1% of coronary angiograms completed for evaluation of chest pain. However, these congenital anomalies can be very important clinically depending on the course of the anomalous arteries. Projection x-ray angiography has traditionally been the preferred imaging technique for the diagnosis and characterization of anomalous arteries. However, conventional angiography is considered a flawed gold standard; sometimes the anomalous artery is not well visualized, and the declining use of pulmonary artery catheters during conventional angiography makes it more difficult to discern the anterior versus posterior trajectory of the anomalous artery.

Given the low incidence of this condition, it is not surprising that there is relatively limited literature compared to the literature addressing the diagnosis of CAD. Existing studies consist of case series comparing CCTA with conventional angiography. As noted in the review of the literature by Bluemke and colleagues, seven case series enrolling a total of 161 patients have been reported. In all but one study, the CCTA correctly identified the anomalous artery, with one exception where 29 of 30 of the arteries were correctly identified. However, none of the studies discussed the impact on therapeutic decisions. Even though the literature focuses on diagnostic accuracy as opposed to final health outcome, in this specific situation the limited outcome of diagnostic accuracy is considered adequate to validate the medical necessity of CCTA to evaluate anomalous coronary arteries when conventional angiography is non-diagnostic and when the result will impact treatment. Unlike CCTA as a technique to diagnose CAD, in this situation conventional angiography is considered a flawed gold standard and CCTA can provide valuable anatomic information when the angiography is considered equivocal.

A writing group deployed by the Working Group Nuclear Cardiology and Cardiac CT of the European Society of Cardiology and the European Council of Nuclear Cardiology published a report on Cardiac Computed Tomography in which the following is noted:

The robust visualization and classification of anomalous coronary arteries make CTA a first-choice imaging modality for the investigation of known or suspected coronary artery anomalies. Radiation dose must be considered often in the young patients, and measures to keep dose as low as possible must be employed (Schroeder, 2008).

Coronary MRA to Detect Coronary Artery Disease (CAD)

Compared to coronary CTA (CCTA), there is more limited literature regarding coronary MRA as a diagnostic technique for CAD. However, the same limitations apply, i.e., the majority of studies are single institution studies reporting diagnostic performance on a per-segment or per-artery basis, as opposed to the more clinically relevant per-patient basis. As reviewed by Bluemke, the negative predictive value in the 17 reviewed studies ranged from 71-96%, which is generally lower than the values reported for CCTA. The Bluemke review notes that the diagnostic accuracy of CCTA favors coronary MRA. However, the main limitation in this literature is the lack of final outcome studies, similar to CCTA.

Coronary MRA to Diagnose Anomalous Coronary Arteries

A total of six studies including 109 patients undergoing MRA to diagnose anomalous coronary arteries were identified in the review by Bluemke. In these studies, coronary MRA correctly identified the anomalous anatomy in 93-100% of cases. Consideration of the medical necessity of coronary MRA for this indication is similar to CCTA for the same indication. Therefore, coronary MRA is considered medically necessary when conventional angiography is either unsuccessful or equivocal.

Background/Overview

Description of Coronary Contrast-enhanced Computed Tomographic Angiography (CCTA)

CCTA is a noninvasive imaging test that requires the use of intravenously administered contrast material and a high-resolution, high-speed CT machine (multi-detector row scanner) to obtain detailed volumetric images of blood vessels. CCTA has been proposed as a noninvasive alternative to invasive coronary angiography, particularly in individuals with an intermediate risk of significant coronary artery disease (CAD).

Description of Coronary Magnetic Resonance Angiography (MRA)
MRA of the coronaries involves the use of traditional MRI technology while a gadolinium-based contrast agent is injected intravenously during image acquisition. This technique does not involve radiation exposure, and the contrast agent, at the dose used for MRA, is not considered nephrotoxic.

Definitions

CAD: coronary artery disease

Coronary contrast-enhanced computed tomography angiography (CCTA): a non-invasive radiological imaging technique that utilizes iodinated contrast agents followed by rapid imaging with a multi-detector row scanner, in order to acquire images of coronary arteries

Magnetic resonance angiography: (MRA) a non-invasive radiological imaging technique that utilizes traditional MRI technology to provide detailed images of blood vessels

Coding

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

When services may be Medically Necessary when criteria are met:

CPT

75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)
	No specific code for cardiac magnetic resonance angiography
	CPT/HCPCS code modifiers:
-26	Professional component
-TC	Technical component

ICD-9 Diagnosis

746.85	Coronary artery anomaly

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above, when criteria are not met, for all other diagnoses, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

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Web Sites for Additional Information

1. National Institutes of Health (NIH). National Heart, Lung, and Blood Institute. Available at: http://www.nhlbi.nih.gov/. Accessed on January 10, 2010.

Index

Document History

Status	Date	Action
Reviewed	02/25/2010	Medical Policy & Technology Assessment Committee (MPTAC)

		review. No change to stance. The Rationale and References were updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes; removed CPT 0146T, 0147T, 0148T, 0149T, 0151T deleted 12/31/2009.
Revised	02/26/2009	MPTAC review. The position statement has been revised to now consider coronary MRA as medically necessary for the evaluation of suspected anomalous coronary arteries when conventional angiography has been unsuccessful or has provided equivocal results and the results could impact treatment. The title was changed to: Coronary Artery Imaging: Contrast-Enhanced Coronary Computed Tomography Angiography (CCTA) and Coronary Magnetic Resonance Angiography (MRA) The Rationale, Background and Coding sections and References have been updated.
Revised	02/21/2008	MPTAC review. No change to stance. The title was changed from Contrast-Enhanced Cardiac Computed Tomography Angiography (CTA) and Cardiac Magnetic Resonance Angiography (MRA) to: Coronary Artery Imaging: Contrast-Enhanced Computed Tomography Angiography (CTA) and Cardiac Magnetic Resonance Angiography (MRA). The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting. References, Coding, and Background sections were updated.
Reviewed	03/08/2007	MPTAC review. No change to stance/criteria. Information in the Rationale section was updated to include comments from the 2006 AHA Scientific Statement (Budoff, 2006). References and Coding sections were also updated.
Revised	12/07/2006	MPTAC review. Position stance was revised to consider CTA medically necessary for the evaluation of suspected anomalous coronary arteries, subject to criteria being met. Also added a statement regarding MRA for evaluation of coronary arteries as investigational/not medically necessary. Rationale, Coding, and Reference sections were also updated.
Reviewed	03/23/2006	MPTAC review. No changes to criteria. References were updated.
	01/01/2006	Updated coding section with 01/01/2006 CPT/HCPCS changes
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
New	04/28/2005	MPTAC initial document development.