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Medical Policy Manual

Topic: Contrast Enhanced Computed Tomographic Angiography (CTA) for Coronary Artery Evaluation

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Contrast-enhanced computed tomographic angiography (CTA) is a noninvasive imaging study that requires the use of intravenously administered contrast material and high-resolution, high-speed CT machinery to obtain detailed images of the coronary blood vessels. CTA is a potential alternative to current diagnostic tests for cardiac ischemia, i.e., non-invasive stress testing and/or coronary angiography. Very short image acquisition times are necessary to avoid blurring artifacts from the rapid motion of the beating heart. Rapid scanning is also helpful so that the volume of cardiac images can be obtained during breath-holding.

Background

The various computed tomographic (CT) imaging devices used to assess coronary arteries include but are not limited to electron beam CT (also known as ultrafast CT) and helical CTs including multi-detector row CT (MDCT) and multi-slice CT (MSCT).

CTA has several important limitations. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory study. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is generally more difficult than

visualization of the proximal and midsegment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

Radiation delivered with current generation scanners utilizing reduction techniques (prospective gating and spiral acquisition) has declined substantially—typically to under 10 mSv. For example, an international registry developed to monitor coronary CTA radiation recently reported a median 2.4 mSv (interquartile range, [IQR]: 1.3 to 5.5) exposure.[1] In comparison, radiation exposure accompanying rest-stress perfusion imaging ranges varies according to isotope used—approximately 5 mSv for rubidium-82 (PET), 9 mSv for sestamibi (SPECT), 14 mSv for F-18 FDG (PET), and 41 mSv for thallium; during diagnostic invasive coronary angiography, approximately 7 mSv will be delivered.[2] EBCT using electrocardiogram (ECG) triggering delivers the lowest dose (approximately 0.7 to 1.1 mSv with 3-mm sections). Any cancer risk due to radiation exposure from a single cardiac imaging test depends on age (higher with younger age at exposure) and gender (greater for women).[3-5] Empirical data suggest that every 10 mSv of exposure is associated with a 3% increase in cancer incidence over 5 years.[6]

MEDICAL POLICY CRITERIA

Note: This policy only addresses the use of contrast-enhanced computed tomographic angiography (CTA) in the evaluation of coronary arteries and does not address the use of CTA for evaluation of cardiac structure and function (e.g. cardiac masses, emergent evaluations of aortic dissection, suspected pulmonary embolism, and structural morphology).

The use of electron beam CT or helical CT to detect coronary artery calcification is addressed in a separate policy, Radiology 6, Computed Tomography to Detect Coronary Artery Calcification.

I. Anomalous Coronary Artery Mapping

Contrast-enhanced computed tomographic angiography (CTA) for evaluation of congenital anomalous (native) coronary arteries in symptomatic patients may be considered **medically necessary**.

II. Evaluation of Coronary Artery Disease in the Emergency Room/Emergency Department Setting

In the emergency room/emergency department setting, contrast-enhanced computed tomographic angiography (CTA) may be considered **medically necessary** for the evaluation of patients with acute chest pain who are without known coronary artery disease.

III. Evaluation of Coronary Artery Disease and All Other Indications

Contrast-enhanced computed tomographic angiography (CTA) of the coronary arteries is considered **investigational** for all other indications, including but not limited to:

A. Diagnosis and screening of coronary artery disease (CAD)

B. Diagnosis of CAD in coronary artery bypass grafts

C. Diagnosis of CAD after percutaneous stent placement

D. Delineation of coronary artery anatomy prior to a cardiovascular procedure

E. Monitoring plaque density to evaluate treatment effect

SCIENTIFIC EVIDENCE

Three indications for cardiac or coronary CTA are considered in the current policy: 1) evaluation of anomalous coronary arteries, 2) patients with acute chest pain without known coronary disease presenting in the emergency room (ER) setting, and 3) evaluation of stable patients with signs and symptoms of CAD in the non-ER setting. In order to evaluate the use of CTA for any of these indications, the scientific evidence must demonstrate how the results of CTA can be used to benefit patient management and impact health outcomes (i.e., clinical utility) compared with the existing standard of care. Randomized trials are needed to reliably make these comparisons and demonstrate the impact of the test on net health outcomes.

Anomalous Coronary Artery Mapping

Several studies have shown that CTA may be able to map the origin and direction of anomalous arteries when conventional angiography cannot.[7-11] Anomalous coronary arteries are an uncommon finding at angiography, occurring in approximately 1% of coronary angiograms completed for evaluation of chest pain. Given the incidence and severity of this rare condition, the present level of evidence is sufficient to support the use of CTA for the presurgical mapping of anomalous coronary arteries when conventional angiography is unsuccessful or equivocal.

Patients with Acute Chest Pain in the Emergency Room/Emergency Department Setting

The evidence on the use of CTA in patients with acute chest pain in the emergency setting consists of many non-randomized clinical trials and several randomized controlled trials, the majority of which are summarized in a recent technology assessment.

Technology Assessment

BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) Assessments from 2005, 2006 and 2011 evaluated the use of contrast-enhanced cardiac computed tomography angiography (CTA) in various clinical settings.[11-13] However, because of the evolving nature of this technology, only the most recent TEC assessment (2011) is discussed in this policy.

The 2011 TEC Assessment examined evidence surrounding the evaluation of patients with acute chest pain and without known coronary artery disease (CAD) and included a discussion of the following literature:

- Two randomized controlled trials (RCTs) and two prognostic studies conducted in emergency settings were considered in this TEC assessment. The first evaluated 197 patients from a single center without evidence of acute coronary syndromes were randomized to coronary CTA (n=99) or usual care (n=98).[14] Over a 6-month follow-up, no cardiac events occurred in either arm. Invasive coronary angiography rates were somewhat higher in the coronary CTA arm (12.1% vs. 7.1%). Diagnosis was achieved more quickly following coronary CTA.
- The second trial (CT-STAT) evaluated a similar sample of 699 randomized patients from 16 centers—361 undergoing coronary CTA and 338 myocardial perfusion imaging (MPI).[15] Over a 6-month follow-up, there were no deaths in either arm: 2 cardiac events in the coronary CTA arm and

1 in the perfusion imaging arm. Invasive coronary angiography rates were similar in both arms (7.2% after coronary CTA; 6.5% after perfusion imaging). A second non-invasive test was obtained more often following coronary CTA (10.2% versus 2.1%), but cumulative radiation exposure in the coronary CTA arm (using retrospective gating) was significantly lower—mean 11.5 versus 12.8 MPI. Time to diagnosis was shorter (mean 3.3 hours) and estimated emergency room costs lower with coronary CTA.

- Two studies reported no cardiac events following a negative coronary CTA in the emergency room after 12 months' (n=481)[16] and 24 months' (n=368)[17] follow-up.

The TEC Assessment made the following observations and conclusions:

- Owing to the negative prognostic value of coronary CTA in this population, the test offers a diagnostic alternative for patients and providers. Evidence obtained in the emergency setting, similar to more extensive results among ambulatory patients, indicates a normal coronary CTA provides a prognosis at least as good as other negative non-invasive tests.
- Other important outcomes that require consideration in comparing technologies include invasive coronary angiography rates, use of a second non-invasive test, radiation exposure, and follow-up of any incidental findings. While there is uncertainty accompanying the limited trial evidence, it is reasonable to conclude that the invasive angiography rate following coronary CTA is similar to that following perfusion imaging. Evidence regarding comparative differences in obtaining a second non-invasive test is limited to CT-STAT and was greater following coronary CTA. Despite that difference, cumulative radiation exposure remained lower in the coronary CTA arm utilizing retrospective gating techniques. Given further reduction realized with prospective gating and other techniques, radiation exposure accompanying coronary CTA will continue to decrease.
- Incidental findings following coronary CTA are common and lead to further testing without evidence for benefit.

Findings from a 2013 systematic review of randomized trials that evaluated CTA in patients with chest pain in the emergency room (ER) setting support the conclusions outlined in the 2011 TEC Assessment.[18]

Randomized Controlled Trial (RCT)

- Subsequent to the 2011 TEC Assessment, Litt and colleagues published results from a RCT on the use of CTA in the emergency department setting.[19] Enrollment of 1,370 patients at low-to-intermediate pre-test risk of CAD took place in 5 centers across the United States. Following enrollment, using a computer-generated randomization method, patients were assigned in a 2:1 fashion to CTA or traditional care (determined on a case-by-case basis for each patient). However, due to a variety of reasons (most commonly, elevated heart rate), CTA was only performed on 85% of patients assigned to CTA (ranging from 67% to 93% of patients depending on treatment center). In addition, 6% of patients assigned to the traditional care group also received CTA and another 36% of the traditional care group did not undergo any objective assessment for CAD.

  Safety was the primary study outcome, characterized as the rate of major adverse cardiac events (MACE; defined as myocardial infarction or cardiac death) in the 30 days following testing. The study was specifically powered to identify whether patients with less than 50% stenosis on CTA had no more than 1% rate of adverse events in the 30 days following testing. Although differences in rates of adverse events were not found between the two groups, the study was not powered to look for between-group differences. The researchers did, however, report between-group differences in

the length of stay and time to diagnosis in diagnostic groups (patients in the CTA group had shorter duration of both of these variables). However, interpretation of these results is limited by the lack of standardized testing in the traditional care group, which limits the ability to compare diagnosis with CTA against a defined diagnostic strategy. Nevertheless, because decreased time to diagnosis and low overall rate of adverse events are suggestive of treatment benefit with CTA, this study does not change the determination reached by the 2011 TEC Assessment.

- Another RCT by Hoffmann and colleagues, compared length of stay and patient outcomes in patients evaluated with CTA versus usual care.[20] In patients in the CTA arm of the trial, the mean length of stay in the hospital was reduced by 7.6 hours and more patients were discharged directly from the emergency department (47% vs 12%, P<0.001). There were no undetected coronary syndromes and no differences in adverse events at 28 days. However, in the CTA arm, there was more subsequent diagnostic testing and higher cumulative radiation exposure. The cumulative costs of care were similar between the two groups.

Conclusion

Overall, the use of coronary CTA in the emergency room setting was found to have a similar negative prognostic value which is equal to other standard tests used to rule out coronary disease. In addition, coronary CTA appears to decrease the time to diagnosis and is associated with low adverse event rates, making it a useful diagnostic tool for ruling-out causes of chest pain in patients without a history of CAD who present to the ER.

Evaluation of Coronary Artery Disease and All Other Indications

The clinical utility of CTA depends on how the results of the study can be used to benefit patient management. The most informative and convincing evidence would accordingly compare outcomes following an anatomic-first (coronary CTA) and functional-first (e.g., perfusion imaging, stress echocardiography) strategies. However, the available evidence consists of non-randomized and/or non-comparative studies of diagnostic accuracy, incidental findings, radiation exposure, and studies of downstream or subsequent testing. Several meta-analyses have been published on the prognostic value of CTA. No randomized controlled trials have been identified on the use of CTA outside the emergency room/emergency department setting.

Diagnostic Performance

The majority of studies examining sensitivity, specificity, and positive and negative predictive values of CTA have significant limitations that do not allow conclusions to be made about the effectiveness of this test for evaluation of CAD in symptomatic or asymptomatic patients.[11,12,21-62] Limitations include one or more of the following:

- Inadequate Study Power

  Studies were not adequately powered to prove equivalence between CTA and conventional angiography. Sample sizes were not determined in advance.

- Potential Bias

  CTA for diagnosis of CAD has largely been evaluated in preselected, high risk patients who were

scheduled for angiography. The ability of CTA to diagnose and prevent angiography in patients with a low to intermediate risk, for which CTA use is proposed, is still unknown. Safety and efficacy for the low to intermediate risk population may be different than for those patients already scheduled for angiography.

Subjects of some studies were convenience samples, limited to patients who agreed to be in the study, subjects scheduled for elective surgery, or availability of the research staff. These patient selection methods do not address selection bias.

Diagnostic performance was analyzed and reported per vessel or per segment rather than per patient in some studies. While vessel or segment-based analyses might be useful in determining treatment decisions about single vessels, decisions about whether to undergo invasive angiography are not made on a vessel-by-vessel basis, but based on all cardiac vessels in the patient as a whole.

Reporting was limited to evaluable coronary artery segments only, with up to 12% of these segments being excluded from analysis. In patients with bypass grafts or stents, evaluation was unreliable or impossible in 13-26% of the segments due to vascular clips or calcification artifacts. Exclusion of these segments from analysis could confound sensitivity and specificity results. For example, in a meta-analysis in which patients from 14 studies were pooled, sensitivity and specificity fell from 90% and 91% to 79% and 81%, respectively when non-assessable segments were included in the analysis.[50]

- Results for the technical validity of CTA, including the sensitivity, specificity, and positive and negative predictive values are inconsistent between studies ranging from a sensitivity of 67% to 100% and a specificity of 49% to 100%.

- In patients with in-stent restenosis, measurements of diameter were smaller on MDCT by 16% to 27% compared with conventional angiography. It is not known how this difference might influence clinical management of the patient.

Incidental Findings

Several studies using 64+ slice scanners were identified.[63-72] Incidental findings were frequent (26.6% to 68.7%) with pulmonary nodules typically the most common finding and cancers rare (approximately 5/1,000 or less). Aglan et al. compared the prevalence of incidental findings when the field of view was narrowly confined to the cardiac structures seen when the entire thorax was imaged. As expected, incidental findings were less frequent in the restricted field (clinically significant findings in 14% versus 24% when the entire field was imaged).[64]

Prognosis

Two meta-analyses and two registry reports have been published on the prognostic value of CTA and are detailed below:

- Hulten et al. performed a meta-analysis of 18 studies (n=9,592) with 3 or more months' follow-up (median 20 months) enrolling patients with suspected CAD (mean age 59 years, 58% male).[73] Annualized death or myocardial infarction (MI) rates after a normal coronary CTA (no identified stenosis >50%) was 0.15%. The pooled rate included 2 studies of EBCT and 4 that utilized 16 slice scanners; most events in the normal group occurred in one of the EBCT studies.

- Bamberg et al. pooled results from 9 studies (n=3,670) enrolling ≥100 patients with ≥1 year follow-up of patients with suspected CAD (mean age 59.1±2.6 years, 63% male).[74] The pooled annualized event rate (all-cause and cardiac death, MI, unstable angina, revascularization) was 1.1% following a coronary CTA without evidence of significant stenosis; in the 38% of patients without evidence of any atherosclerotic plaque, the annual event rate 0.4%. In comparison, Metz et al. performed a meta-analysis of event rates following a negative myocardial perfusion imaging (MPI) and stress echocardiography.[75] The pooled annual cardiac death and myocardial infarction (MI) rates following negative MPI (17 studies; 8,008 patients) and stress echocardiography (4 studies; 3,021 patients) were 0.45% and 0.51%, respectively. Nevertheless, differences in event rates between these diagnostic strategies may be attributed to differences in testing technology or study protocol of the included studies in each meta-analysis and warrant further study.

- Five separate analyses report on prognostic value of CTA in sub-groups of the CONFIRM Registry (n=14,064 and 23,854 patients).[76-80] Studies indicated that CAD severity, measured by CTA, had incremental prognostic value over left ventricular ejection fraction for predicting all-cause mortality. No or mild CAD diagnosed by CCTA was associated with lower rates of follow-up invasive coronary angiography (ICA) and revascularization, while obstructive CAD diagnosed by CCTA was associated with increased invasive procedures as CAD severity rose. An associated survival benefit was observed in patients with high-risk CAD diagnosed by CCTA who underwent coronary revascularization. In addition, studies found that the absence of detected CAD on CTA was associated with a low rate of incident death and that CAD detected by CTA predicted death or MI across three large ethnicities (Caucasian, African and East Asian). However, interpretation of these findings is limited by the lack of comparator treatment group, without which it is not possible to isolate benefit of testing beyond that offered by the current standard of care. Additionally, the lack of information on pre-test risk of disease, or stratification of outcomes by this variable limits the generalizability of these findings to other patient populations.

- Another analysis of a small multi-center patient registry of CTA (n=2,474) found that when stratified by age and gender, CTA was predictive of adverse events among males and females older than 60 years (but not those younger than 60).[81] This finding may be suggestive of the need for a varied approach to diagnostic testing among younger women. However, because other clinical characteristics differed between the sub-groups (for example, more males than females had diabetes or were current smokers), it is not clear that the difference in prognostic value can be attributed to sex and age alone (versus some unstudied third variable).

Subsequent or Downstream Testing

Whether tests are used to replace or add to others currently in use is addressed in the studies below:

- In an analysis of 2006 data from patients without CAD as recorded in claims, Min et al. found that following MPI, 11.6% of 6,588 patients underwent subsequent MPI, coronary CTA, or invasive angiography; following coronary CTA, 14.6% of 1,647 patients underwent one of those tests.[82]

- More recently, Cheezum et al. retrospectively identified 241 symptomatic patients without known CAD undergoing coronary CTA and matched them by age and gender to 252 also symptomatic patients undergoing MPI.[83] Downstream testing was less frequent following coronary CTA than MPI (11.5% vs. 17.0%), as well as invasive coronary angiogram (ICA; 3.3% vs. 8.1%).

- Shreibati et al. conducted a retrospective cohort study using 2005 to 2008 Medicare claims of 282,830 patients undergoing non-emergent, noninvasive testing for CAD.[84] Cardiac catheterization was more frequent in patients evaluated by coronary CTA (22.9%) compared with MPI (12.1%) (adjusted OR 2.2 [95% CI: 2.1 to 2.3]). Percutaneous coronary intervention (PCI) was also more common—7.8% versus 3.4% (adjusted OR 2.5 (95% CI: 2.3 to 2.7) compared to CTA. The study was limited by a lack of follow-up for cardiac events.

- A prospective multicenter registry study, Study of Myocardial Perfusion and Coronary Anatomy Imaging Roles in Coronary Artery Disease (SPARC), evaluated imaging modalities from 1703 patients with no history of CAD.[85] Authors reported that angiography was more frequent within 90 days following coronary CTA (13.2%) compared with SPECT (4.3%) or PET (11.1%). Although observational study results vary and selection bias may be present, angiography rates appear higher following coronary CTA.

- Yamauchi et al. compared outcomes in 2825 patients with stable angina evaluated for suspected CAD who underwent initial CTA (n=625), MPI (n=1205), or angiography (n=950).[86] Average follow-up was 1.4 years. In a Cox proportional hazards model adjusted for potential confounders, the relative hazard of major cardiac events following MPI or coronary CTA were lower than following angiography; annual rates of 2.6%, 2.1%, and 7.0% respectively. Revascularization rates were higher following coronary CTA than MPI (OR 1.6; 95% CI: 1.2 to 2.2). However, the results are limited by the observational nature of the data and difficulty controlling for selection bias in a conventional analysis.

- Finally, coronary CTA and ICA in Ontario are centralized to a single academic center in Ottawa, which allowed investigators to examine coronary CTA accuracy concurrent with the impact on ICA referrals.[87] Consecutive patients (n=3,538) were evaluated by ICA during 14 months before and in the 12 months after (n=3,479) coronary CTA introduction. The rate of normal ICA decreased from 31.5% before to 26.8% after coronary CTA introduction (p=0.003). During the same period at 3 other centers without coronary CTA programs, normal ICA rates increased from 30.0% to 31.0%.

Nevertheless, no consensus has been reached regarding use of subsequent testing following CTA. Additional studies are needed to establish whether subsequent testing is required at higher rates for CTA versus other testing options, and whether this is true for all sub-populations undergoing testing.

Radiation Exposure

Exposure to ionizing radiation increases lifetime cancer risk.[88] Three studies have estimated excess cancer risks due to radiation exposure from coronary CTA[4,5,89]

- Assuming a 16-mSv dose, Berrington de Gonzalez et al. estimated that the 2.6 million coronary CTAs performed in 2007 would result in 2,700 cancers or approximately 1 per 1,000.[89]

- Smith-Bindman et al. estimated cancer would develop in 1 of 270 women and 1 of 600 men age 40 undergoing coronary CTA with a 22-mSv dose.[5]

- Einstein et al. employed a standardized phantom to estimate organ dose from 64-slice coronary CTA.[4] With modulation and exposures of 15 mSv in men and 19 mSv in women, the calculated lifetime cancer risk at age 40 was 7 per 1,000 men (1 in 143) and 23 per 1,000 women (1 in 43).

However, estimated radiation exposure used in these studies is considerably higher than what is received with current scanners—now typically under 10 mSv and often less than 5 mSv with contemporary machines and radiation reduction techniques. For example, in the 47-center PROTECTION I study enrolling 685 patients, the mean radiation dose was 3.6 mSv, using a sequential scanning technique.[90] Thus, risk of cancer is likely to decrease with advances in scanning technology, but is still likely to remain present. Therefore, evaluation of this diagnostic technique must take into account risk of cancer development, along with any potential positive impacts of testing, in determining the net benefit of CTA.

Conclusion

A number of multicenter studies have evaluated the diagnostic accuracy of CTA for diagnosing coronary ischemia in an outpatient population. In general, these studies report high sensitivity and specificity, but there is some variability in these parameters across studies. Use of CTA in this situation does not have the same advantage of improving the efficiency of diagnosis as it does in the emergency setting. In addition, there is evidence that angiography rates are higher following coronary CTA. Evidence defining comparative outcomes outside the emergency room setting is limited. Without additional comparative studies, the risk/benefit ratio for this test depends on the diagnostic accuracy, the impact of incidental findings, and the amount of radiation exposure. Given the uncertainty in these parameters, it is not possible to conclude that the use of CTA in the non-emergency room setting leads to improved outcomes compared to alternative strategies. Randomized controlled trials are needed to evaluate intermediate - to high- risk patients outside the emergency setting and to compare how CTA impacts the clinical management of these patients.

Clinical Practice Guidelines

American College of Cardiology Foundation (ACCF)/ American College of Physicians (ACP)/American Association for Thoracic Surgery (AATS)/ Preventive Cardiovascular Nurses Association (PCNA)/ Society for Cardiovascular Angiography and Interventions (SCAI)/and Society of Thoracic Surgeons (STS)[91]

These joint 2012 evidence-based guidelines, regarding the management of patients with stable ischemic heart disease made the following recommendations:

- For assessment of cardiovascular risk in patients presenting with chest pain:
    - "CCTA might be reasonable for patients with an intermediate pretest probability of (ischemic heart disease) IHD who have at least moderate physical functioning or no disabling comorbidity." (Level B Evidence; Class IIb)*
    - "CCTA is reasonable for patients with a low to intermediate pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity." (Level B Evidence; Class IIa)*
    - "CCTA is reasonable for patients with an intermediate pretest probability of IHD who a) have continued symptoms with prior normal test findings, or b) have inconclusive results from prior exercise or pharmacological stress testing, or c) are unable to undergo stress with nuclear MPI or echocardiography." (Level C Evidence; Class IIa) *

- For the assessment of cardiovascular risk in asymptomatic adults :

    - "CCTA may be reasonable for risk assessment in patients with SIHD who are able to exercise to an adequate workload but have an uninterpretable ECG." (Level B Evidence; Class IIa) *

    - "CCTA can be useful as a first-line test for risk assessment in patients with SIHD who are unable to exercise to an adequate workload regardless of interpretability of ECG." (Level C Evidence; Class IIa) *

    - "CCTA can be useful for risk assessment in patients with SIHD who have an indeterminate result from functional testing." (Level C Evidence; Class IIa) *

    - "CCTA might be considered for risk assessment in patients with SIHD unable to undergo stress imaging or as an alternative to invasive coronary angiography when functional testing indicates a moderate- to high-risk result and knowledge of angiographic coronary anatomy is unknown." (Level C Evidence; Class IIb) *

    - "CCTA for assessment of patency of CABG or of coronary stents 3 mm or larger in diameter might be reasonable in patients with known SIHD who have new or worsening symptoms not consistent with UA, irrespective of ability to exercise." (Level B Evidence; Class IIb) *

    - "CCTA might be reasonable in patients with known SIHD who have new or worsening symptoms not consistent with UA, irrespective of ability to exercise, in the absence of known moderate or severe calcification or if the CCTA is intended to assess coronary stents less than 3 mm in diameter." (Level B Evidence; Class IIb) *

*Evidence Classification

- Level B Evidence: based on limited populations and data derived from a single randomized trial or nonrandomized studies
- Level C Evidence: based on limited populations and data derived from a single randomized trial or nonrandomized studies
- Class IIa recommendation indicates that additional studies with focused objectives are needed, but benefits outweigh risks
- Class IIb recommendation indicate additional studies with broad objectives are needed, but benefits are equal to or outweigh risks

Appropriate use criteria[92-94] and expert consensus documents[95-97] published jointly by additional specialty groups address coronary CTA in the emergency setting:

> "In the context of the emergency department evaluation of patients with acute chest discomfort, currently available data suggest that coronary CTA may be useful in the evaluation of patients presenting with an acute coronary syndrome (ACS) who do not have either acute electrocardiogram (ECG) changes or positive cardiac markers. However, existing data are limited, and large multicenter trials comparing CTA with conventional evaluation strategies are needed to help define the role of this technology in this category of patients."

American College of Radiology (ACR) [98]

ACR Appropriateness Criteria® published in 2012, assigned a level 8 recommendation (the second highest recommendation, indicating this procedure is "usually appropriate") for the use of CTA in the following patients experiencing acute nonspecific chest pain with low probability of coronary artery disease:

- In patients, in whom anomalous coronary artery is suspected.
- "For pulmonary embolism and thoracic aortic aneurysm/dissection. To rule out pulmonary embolism and evaluate lung pathology."
- "Can be used to assess for coronary atherosclerosis, anomalous coronary artery, and pericardial disease. High negative predictive value will exclude coronary artery disease and allow triage management to focus on more likely diagnoses. To eliminate unnecessary catheterizations."

Summary

Anomalous Coronary Artery Mapping

Contrast-enhanced computed tomographic angiography (CTA) appears to effectively determine the origin and course of anomalous coronary arteries in cases when conventional angiography is unsuccessful. Therefore, CTA may be considered medically necessary for evaluation of congenital anomalous (native) coronary arteries in symptomatic patients.

Patients with Acute Chest Pain in the Emergency Room/Emergency Department Setting

In patients presenting to emergency settings with acute chest pain that is possibly cardiac in origin and with no known history of coronary artery disease (CAD), the net health outcome following coronary contrast-enhanced computed tomographic angiography (CTA) appears at least as good as that obtained following other noninvasive testing strategies. CTA can rule out active coronary disease with a high rate of certainty in patients with low-to-moderate pre-test probabilities of CAD and is an efficient strategy in the emergency setting. Therefore, CTA may be considered medically necessary for use in this patient population.

Evaluation of Coronary Artery Disease and All Other Indications

For other indications such as evaluation of patients with stable chest pain, the balance of potential benefits and harms remains uncertain owing largely to the lack of direct comparative evidence. A fundamental difficulty with current, albeit substantial indirect evidence surrounding contrast-enhanced computed tomographic angiography (CTA) is that decision making has historically relied on a strategy of functional non-invasive testing followed by invasive angiography to define anatomy. Evidence is insufficient to determine whether coronary CTA decreases the rate of normal invasive coronary angiograms in the diagnostic evaluation of coronary artery disease (CAD). Studies in representative populations that examined the frequency of repeated testing are lacking. Non-cardiac findings are frequent, but the consequences with respect to benefits and harms have received limited scrutiny. It is uncertain whether outcomes are improved with CTA compared with alternative tests; therefore, the use of CTA for this patient population is considered investigational.

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CROSS REFERENCES

Computed Tomography to Detect Coronary Artery Calcification, Radiology, Policy No. 6

Ultrasonographic Measurement of Carotid Artery Intima-Media Thickness as an Assessment of Atherosclerosis, Radiology, Policy No. 37

CODES	NUMBER	DESCRIPTION
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)
HCPCS	None	