Contrast-enhanced coronary computed tomography angiography (CCTA) may be considered medically necessary for evaluation of patients without known coronary artery disease and acute chest pain in the emergency department setting.

Contrast-enhanced coronary computed tomography angiography (CCTA) may be considered medically necessary for evaluation of patients with stable chest pain and meeting guideline criteria for a noninvasive test in the outpatient setting (see Policy Guidelines).

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

Contrast-enhanced coronary computed tomography angiography (CCTA) for coronary artery evaluation is considered investigational for all other indications.

The 2012 collaborative medical association guidelines for the diagnosis and management of patients with stable heart disease (Fihn et al, 2012) list several class I recommendations on use of noninvasive testing in patients with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general, patients with at least intermediate risk (10%-90% risk by standard risk prediction instruments) are recommended to have some type of test, the choice depending on interpretability of the electrocardiogram, capacity to exercise, and presence of comorbidity.

Coding
The following code is a category I CPT code for this service:
- **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)

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

Related Policies
- Computed Tomography to Detect Coronary Artery Calcification
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

Rationale

Background

Coronary Artery Disease

Various noninvasive tests are used to diagnose coronary artery disease (CAD). They can be broadly classified as those that detect functional or hemodynamic consequences of obstruction and ischemia (exercise treadmill testing, myocardial perfusion imaging, stress echocardiography with or without contrast), and others that identify the anatomic obstruction itself (coronary computed tomography angiography [CCTA], coronary magnetic resonance imaging). Functional testing involves inducing ischemia by exercise or pharmacologic stress and detecting its consequences. However, not all patients are candidates. For example, obesity or obstructive lung disease can make obtaining echocardiographic images of sufficient quality difficult. Conversely, the presence of coronary calcifications can impede detecting coronary anatomy with CCTA.

Diagnostic Testing

Some tests will be unsuitable for particular patients. The presence of dense arterial calcification or an intracoronary stent can produce significant beam-hardening artifacts and may preclude a satisfactory imaging. The presence of an uncontrolled rapid heart rate or arrhythmia hinders the ability to obtain diagnostically satisfactory images. Evaluation of the distal coronary arteries is more difficult than the visualization of the proximal and mid-segment coronary arteries due to greater cardiac motion and the smaller caliber of coronary vessels in distal locations.

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

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

**Coronary Arterial Anomalies**
Congenital coronary arterial anomalies (i.e., abnormal origin or course of a coronary artery) that lead to clinically significant problems are relatively rare. Symptomatic manifestations may include ischemia or syncope. Clinical presentation of anomalous coronary arteries is difficult to distinguish from other more common causes of cardiac disease; however, an anomalous coronary artery is an important diagnosis to exclude, particularly in young patients who present with unexplained symptoms (e.g., syncope). There is no specific clinical presentation to suggest a coronary artery anomaly.

**Radiation Exposure**
Levels of radiation delivered with current generation scanners using reduction techniques (prospective gating and spiral acquisition) have declined substantially—typically to under 10 mSv. For example, an international registry developed to monitor CCTA radiation exposure has reported a median of 2.4 mSv (interquartile range, 1.3-5.5). By comparison, radiation exposure accompanying rest-stress perfusion imaging varies by isotope used—approximately 5 mSv for rubidium 82 (positron emission tomography), 14 mSv for fluorine 18 fluorodeoxyglucose, 9 mSv for sestamibi (single-photon emission computed tomography), and 41 mSv for thallium; during diagnostic invasive coronary angiography, approximately 7 mSv is delivered. Electron-beam computed tomography using electrocardiogram triggering delivers the lowest dose (0.7-1.1 mSv with 3-mm sections). Any cancer risk due to radiation exposure from a single cardiac imaging test depends on age (higher with younger age at exposure) and sex (greater for women). Empirical data have suggested that every 10 mSv of exposure is associated with a 3% increase in cancer incidence over 5 years.

The use of electron-beam computed tomography or helical computed tomography to detect coronary artery calcification is addressed separately (Blue Shield of California Medical Policy: Computed Tomography to Detect Coronary Artery Calcification).

**Literature Review**
This review has been informed by several Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (2005, 2006, 2011).

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

**Patients With Acute Chest Pain Presenting in the Emergency Setting**
**Clinical Context and Test Purpose**
The purpose of coronary computed tomography angiography (CCTA) imaging in patients with acute chest pain is to diagnose coronary artery obstruction and guide treatment decisions.

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

The following PICOTS were used to select literature to inform this review.
Patients
The relevant population of interest is patients with acute chest pain and suspected coronary artery disease (CAD) who are at an intermediate to low risk.

Interventions
The intervention of interest is CCTA.

Comparators
The following tests and practices are currently being used to make decisions about managing acute chest pain and suspected CAD: standard emergency department (ED) care and alternative noninvasive testing including stress tests.

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

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

Setting
CCTA is administered in hospital ED setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

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

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

Systematic Reviews
Gongora et al (2018) published a meta-analysis of 10 RCTs (total N=6285 patients) comparing CCTA with the standard of care (SOC) in patients with acute chest pain in an ED setting or an inpatient setting. Pooled results suggested that CCTA results in more frequent revascularization and ICA without reducing the risk of adverse cardiac events. Among the limitations of the review
were the heterogeneity of SOC across assessed studies, the possibility of publication bias due to the small number of trials available, and the presence of only a few studies that prespecified downstream testing criteria following CCTA results. See Tables 1 and 2 for review characteristics and results.

**Table 1. Characteristics of Systematic Reviews Assessing CCTA in ED Settings**

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration, mo</th>
</tr>
</thead>
</table>

ED: emergency department; CCTA: coronary computed tomographic angiography; RCT: randomized controlled trial.

**Table 2. Results of Systematic Reviews Comparing CCTA With SOC in ED Settings**

<table>
<thead>
<tr>
<th>Study</th>
<th>ICA (CCTA vs SOC)</th>
<th>Revascularization (CCTA vs SOC)</th>
<th>All-Cause Mortality (CCTA vs SOC)</th>
<th>All-Cause MI (CCTA vs SOC)</th>
<th>All-Cause MACE (CCTA vs SOC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gongora et al (2018)</td>
<td>Higher incidence in CCTA</td>
<td>Higher incidence in CCTA</td>
<td>No significant between-group difference</td>
<td>No significant between-group difference</td>
<td>No significant between-group difference</td>
</tr>
<tr>
<td>RR (95% CI)</td>
<td>1.32 (1.07 to 1.63)</td>
<td>1.77 (1.35 to 2.31)</td>
<td>0.48 (0.17 to 1.36)</td>
<td>0.82 (0.49 to 1.39)</td>
<td>0.98 (0.67 to 1.43)</td>
</tr>
<tr>
<td>p</td>
<td>0.01</td>
<td>&lt;0.001</td>
<td>0.17</td>
<td>0.47</td>
<td>0.92</td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomographic angiography; CI: confidence interval; ED: emergency department; ICA: invasive coronary angiography; MACE: major adverse cardiac event; MI: myocardial infarction; RR: relative risk; SOC: standard of care.

Skelly et al (2016), conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality that assessed noninvasive testing for CAD. Reviewers found that:

- After CCTA, clinical outcomes for patients with an intermediate pretest risk
  - were similar when compared with usual care or functional testing (low-to-moderate strength of evidence).
  - were similar when compared with single-photon emission computed tomography (low strength of evidence).
- After CCTA, referral for ICA and revascularization
  - was more common than after functional testing (high strength of evidence).
  - was similar compared with single-photon emission computed tomography and usual care (low strength of evidence).
- After CCTA, additional testing in the ED setting
  - was less common compared with usual care (moderate strength of evidence).
  - was more common than after single-photon emission computed tomography (high strength of evidence).
- After CCTA, hospitalization
  - was less common compared with usual care in the ED setting (moderate to low strength of evidence).
  - was similar to functional testing in the outpatient setting (moderate strength of evidence).

Overall, reviewers found no clear differences between strategies for clinical or management outcomes, although CCTA could lead to a higher frequency of referral for ICA and revascularization.

A TEC Assessment (2011) examined evidence on patients with acute chest pain and without known CAD.

**Randomized Controlled Trials**

RCTs and prospective observational studies were identified. Tables 3 and 4 summarize the characteristics and results of RCTs assessing CCTA procedures conducted in ED settings.
Table 3. Characteristics of RCTs Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levsky et al (2018)</td>
<td>U.S.</td>
<td>1</td>
<td>2011-2016</td>
<td>Patients with acute chest pain or pressure for whom noninvasive testing requested</td>
<td>201 to CCTA</td>
</tr>
<tr>
<td>Hamilton-Craig et al (2014); CT-COMPARE</td>
<td>Australia</td>
<td>1</td>
<td>2010-2011</td>
<td>Men ≥30 y or women ≥40 y presenting to ED with a acute undifferentiated chest pain</td>
<td>322 to CCTA</td>
</tr>
<tr>
<td>Linde et al (2013); CATCH</td>
<td>Denmark</td>
<td>1</td>
<td>2010-2013</td>
<td>Patients with suspected NSTE-ACS but normal ECG and troponins; discharged within 24 h needing further risk stratification</td>
<td>299 to CCTA</td>
</tr>
<tr>
<td>Litt et al (2012); AC RIN-PA</td>
<td>U.S.</td>
<td>5</td>
<td>2009-2011</td>
<td>Symptoms consistent with possible ACS; &gt;30 y; low risk of MI</td>
<td>908 to CCTA</td>
</tr>
<tr>
<td>Hoffmann et al (2012); ROMICAT II</td>
<td>U.S.</td>
<td>9</td>
<td>2010-2012</td>
<td>Chest pain or angina equivalent &lt;24 h before ED presentation; 40-74 y; sinus rhythm; warranting further risk stratification</td>
<td>50 to CCTA</td>
</tr>
<tr>
<td>Goldstein et al (2011); CT-STAT</td>
<td>U.S.</td>
<td>16</td>
<td>2007-2008</td>
<td>Chest pain &lt;12 h; ≥25 y; low risk of complications; no sign of ischemia at enrollment</td>
<td>361 to CCTA</td>
</tr>
<tr>
<td>Goldstein et al (2007)</td>
<td>U.S.</td>
<td>1</td>
<td>2005</td>
<td>Chest pain or angina-like symptoms &lt;12 h; ≥25 y; low risk of complications</td>
<td>99 to MSCT</td>
</tr>
</tbody>
</table>


Levsky et al (2018) published an RCT: in the CCTA arm, 39 (19%) patients were hospitalized, compared with 22 (11%) patients of the stress echocardiography arm, resulting in a difference of 8% (95% CI, 1% to 15%; p = 0.026). Median length of stay in the hospital was longer for the CCTA arm (58 hours vs 34 hours; p = 0.002, respectively). There was no significant difference between the CCTA and stress echocardiography arms in terms of major adverse cardiac events (MACE; including death): respectively, MACE occurred in 11 CCTA patients and 7 stress echocardiography patients (p = 0.47) over a median follow-up of 24 months. The median complete initial work-up radiation exposure for the CCTA arm was 6.4 mSv (interquartile range, 5.3-7.8 mSv), significantly more than that of stress echocardiography (0 mSv; p < 0.001). The trial had a number of limitations, including the single-center design and omission of high sensitivity troponin assays.

Hamilton-Craig et al (2014) reported on the CT-COMPARE trial, which assessed the length of stay and patient costs in 562 patients presenting to the ED with low-to-intermediate risk chest pain who received CCTA or exercise stress testing. Length of stay was significantly reduced in the CCTA patients compared with the exercise testing patients. Clinical outcomes at 30 days and at 12 months did not differ.

Linde et al (2013) reported on the CATCH trial, which randomized 600 patients to a CCTA-guided strategy or to SOC. For the CCTA-guided strategy, referral for ICA required coronary stenosis greater than 70%. This trial differed in design from the others because patients had been
discharged from the ED, and if there was intermediate stenosis (50%-70%) on CCTA, a stress test was performed.

Litt et al (2012) reported on the AC RIN-PA trial, which also evaluated the safety of CCTA in patients in the ED.\textsuperscript{17} Although the trial was a randomized comparison with traditional care, the principal outcome was safety after negative CCTA examinations. No patients who had negative CCTA examinations (n=460) died or had a myocardial infarction (MI) within 30 days. Compared with traditional care, patients in the CCTA group had higher rates of discharge from the ED (49.6% vs 22.7%) and higher rates of detection of coronary disease.

Hoffmann et al (2012) reported on the ROMICAT II trial, which compared the length of stay with outcomes in 549 patients evaluated using CCTA or usual care.\textsuperscript{18} For the 50 patients in the CCTA arm, mean hospital length of stay was reduced by 7.6 hours, and more patients were discharged directly from the ED (47% vs 12%). There were no undetected coronary syndromes or differences in adverse events at 28 days. However, in the CCTA arm, there was more subsequent diagnostic testing and higher cumulative radiation exposure.

Goldstein et al (2011) reported on the CT-STAT trial, which evaluated a similar sample of 699 patients.\textsuperscript{19} Over a 6-month follow-up, there were no deaths in either arm; there were 2 cardiac events in the CCTA arm and one in the perfusion imaging arm. A second noninvasive test was obtained more often after CCTA (10.2% vs 2.1%), but cumulative radiation exposure in the CCTA arm (using retrospective gating) was significantly lower (mean, 11.5 mSv vs 12.8 mSv).

Goldstein et al (2007) randomized 197 patients without evidence of acute coronary syndromes to CCTA (n=99) or usual care (n=98).\textsuperscript{20} Over a 6-month follow-up, no cardiac events occurred in either arm. Diagnosis was achieved more quickly after CCTA.

### Table 4. Summary of Results of RCTs Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study</th>
<th>ICA (CCTA vs Control), %</th>
<th>Diagnostic Accuracy (CCTA vs Control), % (a)</th>
<th>MI in Negative CCTA Arm</th>
<th>Median Diagnostic Time (CCTA vs Control), h(b)</th>
<th>Time FU, mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levsky et al (2018)\textsuperscript{14}</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>5.4 vs 4.7\textsuperscript{d}</td>
<td>1 and 12</td>
</tr>
<tr>
<td>Hamilton-Craig et al (2014)\textsuperscript{15}</td>
<td>9.0 vs 4.2</td>
<td>94%/99% vs 83%/91%</td>
<td>0</td>
<td>13.5 vs 20.7\textsuperscript{d}</td>
<td>1 and 12</td>
</tr>
<tr>
<td>Linde et al (2013)\textsuperscript{16}</td>
<td>17 vs 12</td>
<td>71 vs 36\textsuperscript{e}</td>
<td>0</td>
<td>NR</td>
<td>4</td>
</tr>
<tr>
<td>Litt et al (2012)\textsuperscript{17}</td>
<td>5.1 vs 4.2</td>
<td>NR</td>
<td>0</td>
<td>18.0 vs 24.8</td>
<td>1</td>
</tr>
<tr>
<td>Hoffmann et al (2012)\textsuperscript{18}</td>
<td>12.0 vs 21.0</td>
<td>NR</td>
<td>0</td>
<td>5.8 vs 21.0</td>
<td>1</td>
</tr>
<tr>
<td>Goldstein et al (2011)\textsuperscript{19}</td>
<td>6.6 vs 6.2</td>
<td>76.9 vs 54.5</td>
<td>0</td>
<td>2.9 vs 6.2</td>
<td>6</td>
</tr>
<tr>
<td>Goldstein et al (2007)\textsuperscript{20}</td>
<td>12.1 vs 7.1</td>
<td>88.9 vs 98.0</td>
<td>0</td>
<td>3.4 vs 15.0</td>
<td>6</td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomographic angiography; ED: emergency department; FU: follow-up; HR: hazard ratio; ICA: invasive coronary angiography; MI: myocardial infarction; NR: not reported; RCT: randomized controlled trial.

- \(a\) Confirmed with angiographic and clinical results.
- \(b\) Time from randomization to definitive diagnosis.
- \(c\) Reporting the sensitivity/specificity for CCTA vs exercise stress electrocardiogram for acute coronary syndrome with stenosis >70%.
- \(d\) Refers to length of stay rather than time to diagnosis.
- \(e\) Positive predictive value for CCTA vs standard of care.

The purpose of the gaps tables (see Tables 5 and 6) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.
### Table 5. Relevance Gaps for RCTs Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levsky et al (2018)</td>
<td>4. Limited applicability to men &lt;30 y and women &lt;40 y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hamilton-Craig et al (2014)</td>
<td>4. Limited to patients 40-74 y; may not be relevant for younger or older individuals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linde et al (2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Litt et al (2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

CCTA: coronary computed tomographic angiography; ED: emergency department; ICA: invasive coronary angiography; RCT: randomized controlled trial.

**Population key:**
1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

**Intervention key:**
1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

**Comparator key:**
1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.

**Outcomes key:**
1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).

**Follow-Up key:**
1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

### Table 6. Study Design and Conduct Gaps of RCTs Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Blinding</th>
<th>Delivery of Test</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamilton-Craig et al (2014)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Not powered to compare outcomes</td>
<td></td>
</tr>
<tr>
<td>Linde et al (2013)</td>
<td>1. Only patients and clinicians blinded to treatment allocation</td>
<td></td>
<td></td>
<td></td>
<td>2. Not powered to detect differences in secondary outcomes (intermediate cardiac events)</td>
<td></td>
</tr>
<tr>
<td>Litt et al (2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Due to low incidence of events, not powered for primary outcome (safety)</td>
<td></td>
</tr>
<tr>
<td>Hoffmann et al (2012)</td>
<td>1. No blinding to treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation

Study Selection
- Goldstein et al (2011)\(^1\), 10.3% of patients lost to follow-up
- Goldstein et al (2007)\(^2\), 1. Power calculations not reported

Blinding
- Not blinded to results of reference or other comparator tests

Delivery of Test
- Timing of delivery of index or reference test not described
- Timing of index and comparator tests not same
- Procedure for interpreting tests not described

Selective Reporting
- Not registered
- Evidence of selective reporting
- Evidence of selective publication

Data Completeness
- Inadequate description of indeterminate and missing samples
- High number of samples excluded
- High loss to follow-up or missing data

Statistical
- Confidence intervals and/or p values not reported
- Comparison to other tests not reported

Follow-Up Studies
Linde et al (2015) reported long-term follow-up\(^3\) from the CATCH trial.\(^4\) Results from long-term follow-up studies are tabulated in Table 7.

Table 7. Results of Follow-Up Studies of RCTs

<table>
<thead>
<tr>
<th>Study</th>
<th>Initial Study Design</th>
<th>Follow-Up Duration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linde et al (2015)(^5)</td>
<td>RCT (CATCH)</td>
<td>18.7 mo (IQR, 16.8-20.1)</td>
<td>In the CCTA group (n=285), there were 5 MACE vs 14 MACE in the SOC group (n=291) (HR=0.36; 95% CI, 0.16 to 0.95; p=0.04)</td>
</tr>
<tr>
<td>Schlett et al (2011)(^6)</td>
<td>RCT (ROMICAT)</td>
<td>2 y</td>
<td>Of 333 patients without CAD detected by CCTA, none had a MACE event during follow-up</td>
</tr>
</tbody>
</table>

ACS: acute coronary syndrome; AMI: acute myocardial infarction; CAD: coronary artery disease; CCTA: coronary computed tomographic angiography; CI: confidence interval; ED: emergency department; HR: hazard ratio; IQR: interquartile range; MACE: major adverse cardiac event; SOC: standard of care.

Nonrandomized Studies
Durand et al (2017) compared the diagnostic performance of dobutamine-stress echocardiography (DSE) with CCTA in 217 adults.\(^7\) Patients had normal measurements of troponin I or T, and electrocardiograph results. All patients received DSE and CCTA, with only 75 (34.6%) patients receiving ICA, which served as the reference test. The primary endpoint was the diagnostic accuracy of the tests for detecting coronary stenosis greater than 50%. Forty-nine (22.6%) patients had a positive CCTA while 33 (15.2%) patients had a positive DSE. A negative CCTA result was reported in 144 (66.4%) patients, and 146 (67.3%) had a negative DSE result. Overall, CCTA was more sensitive than DSE in detecting CAD, while specificity was similar between tests. At 6 months, no patients had died or received a diagnosis of MI, but 1 patient presented with acute coronary syndrome whose diagnosis was initially missed. No limitations were identified. Tables 8 and 9 summarize the trial characteristics and results.

Table 8. Key Nonrandomized Trials Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durand et al (2017)(^8)</td>
<td>Prospective head-to-head multicenter</td>
<td>France</td>
<td>NR</td>
<td>Adults treated at ED for chest pain &lt;24 h after symptom onset</td>
<td>CCTA DSE</td>
<td>6 mo</td>
<td></td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomographic angiography; DSE: dobutamine-stress echocardiography; ED: emergency department; NR: not reported
Table 9. Results of Key Nonrandomized Trials Assessing CCTA in ED Settings

<table>
<thead>
<tr>
<th>Study</th>
<th>Diagnostic Accuracy</th>
<th>Incidence of MI</th>
<th>ICA, n (%)&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CCTA&lt;sup&gt;a&lt;/sup&gt;</td>
<td>DSE</td>
<td></td>
</tr>
<tr>
<td>Durand et al (2017)&lt;sup&gt;23&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>217</td>
<td>217</td>
<td>None during FU</td>
</tr>
<tr>
<td>Sensitivity, %</td>
<td>96.9</td>
<td>51.6</td>
<td></td>
</tr>
<tr>
<td>Specificity, %</td>
<td>48.3</td>
<td>46.7</td>
<td></td>
</tr>
<tr>
<td>PLR (95% CI)</td>
<td>2.09 (1.36 to 3.11)</td>
<td>1.03 (0.62 to 1.72)</td>
<td></td>
</tr>
<tr>
<td>NLR (95% CI)</td>
<td>0.07 (0.01 to 0.52)</td>
<td>1.10 (0.63 to 1.96)</td>
<td></td>
</tr>
</tbody>
</table>


<sup>a</sup> Of detected coronary stenosis >50%.

<sup>b</sup> Number of patients who received ICA.

**Section Summary: Acute Chest Pain Presenting in the Emergency Setting**

The high negative predictive value of CCTA in patients presenting to the ED with chest pain permits ruling out coronary disease with high accuracy. The efficiency of the workup is improved because patients are safely and quickly discharged from the ED with no adverse outcomes among patients with negative CCTA examinations.

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

**Patients With stable chest pain and Suspected Coronary Artery Disease**

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

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

**Clinical Context and Test Purpose**

The purpose of CCTA in patients with stable chest pain and suspected CAD is to diagnose coronary artery obstruction and guide treatment decisions.
The question addressed in this evidence review is: Does the use of CCTA improve the net health outcome of patients with stable chest pain?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with stable chest pain and suspected CAD who are at an intermediate to low risk and meet guideline criteria for noninvasive testing.

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

**Comparators**
The following tests and practices are currently being used to make decisions about managing stable chest pain: noninvasive testing including exercise electrocardiography, myocardial perfusion imaging (MPI), and stress echocardiography, and standard care.

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

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

**Setting**
CCTA is administered in a cardiology clinic setting equipped with standard noninvasive testing for CAD and CCTA.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**Clinically Valid**
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

There is a fairly large body of evidence evaluating the diagnostic characteristics of CCTA for identifying coronary lesions. The best estimate of the diagnostic characteristics of CCTA can be obtained from recent meta-analyses and systematic reviews. Table 10 shows ranges of sensitivity and specificity for functional noninvasive tests from studies of the diagnosis and management of stable angina reviewed by Fihn et al (2012). Sensitivities tended to range between 70% and 90% depending on the test and study, and specificities ranged between 70% and 90%.

For CCTA, estimates of sensitivity from various systematic reviews are considerably higher (see Table 11). The guideline statement from Fihn et al (2012) cited studies reporting sensitivities between 93% and 97%. A systematic review by Ollendorf et al (2011) of 42 studies showed a summary sensitivity estimate of 98% and a specificity of 85%. A meta-analysis of 8 studies conducted by the Health Quality Ontario (2010) showed a summary sensitivity estimate of 97.7% and a specificity of 79%. In the meta-analysis by Nielsen et al (2014), sensitivity rates for CCTA varied between 98% and 99% (depending on the analysis group).
Table 10. Sensitivity and Specificity Estimates for Functional Noninvasive Tests From Guidelines

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

Adapted from Fihn et al (2012).24

Table 11. Sensitivity and Specificity Estimates for CCTA From Guidelines and Meta-Analyses

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Sensitivity (Range or Single Estimates), %</th>
<th>Specificity (Range or Single Estimates), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Quality Ontario (2010)</td>
<td>Meta-analysis</td>
<td>97.7</td>
<td>79</td>
</tr>
</tbody>
</table>

CCTA: coronary computed tomography angiography.

Case Series
Sandstedt et al (2018) published a case series evaluating 1205 patients with suspected CAD who underwent CCTA at a single center.28 Most patients had normal findings (n=668 [55.4%]). Of the 218 patients who underwent ICA, 149 patients had obstructive stenosis, 49 patients had nonobstructive stenosis, and 20 patients did not have evidence of stenosis. The study had several limitations, including a high number of exclusions because of poor image quality, a single-reader clinical evaluation, and limitations inherent of a single-center study. Tables 12 and 13 summarize series characteristics and results.

Table 12. Characteristics of Key Case Series

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Participants</th>
<th>Treatment Delivery</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandstedt et al</td>
<td>Sweden</td>
<td>Suspected CAD</td>
<td>CCTA</td>
<td>7.5 y (median 3.1 y; IQR, 425-1793 d)</td>
</tr>
<tr>
<td>(2018)</td>
<td></td>
<td>without previous CAD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IQR: interquartile range; CAD: coronary artery disease; CCTA: coronary computed tomographic angiography.

Table 13. Results of Key Case Series

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Incidence of CAD</th>
<th>Incidence of MACE</th>
<th>Predictors of MACE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandstedt et al</td>
<td>1205 patients underwent CCTA at a single center; 360 (29.9%) had nonobstructive CAD; 177 (14.7%) had obstructive CAD</td>
<td>0.0% of patients with normal coronary arteries experienced ≥1 MACE; 4.6% of those with nonobstructive CAD; 20.7% of those with obstructive CAD</td>
<td>Nonobstructive CAD predicted MACE (HR=3.48; 95% CI, 1.13 to 10.67; p=0.029)</td>
<td>Obstructive CAD predicted MACE (HR=29.26; 95% CI, 10.86 to 78.83; p&lt;0.001)</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease; CCTA: coronary computed tomographic angiography; CI: confidence interval; HR: hazard ratio; MACE: major adverse cardiac event.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.
**Systematic Reviews**

Foy et al (2017) conducted a systematic review comparing CCTA with functional stress testing for patients with suspected CAD and stable or acute chest pain. In the CCTA arm, there were 10,315 patients, and in the functional stress testing arm, there were 9777 patients; both CCTA and functional stress testing strategies varied among the 13 trials. Overall mortality and cardiac hospitalization did not differ between CCTA and functional stress testing groups. There were fewer cases of MI in the CCTA group than in the functional stress testing group; however, the incidence of ICA and revascularization were higher in the CCTA group. CCTA was associated with an increase in new diagnoses of CAD as well as increased prescription of aspirin and statin therapy. All trials reported a lack of blinding, both of patients and personnel, and overall quality of evidence was moderate, despite a high risk of bias in several studies included. Additional limitations included the lack of available patient-level data, the absence of assessment of time to hospital discharge, and differences in radiation exposure. Tables 14 and 15 summarize review characteristics and results.

**Table 14. Characteristics of Systematic Reviews Assessing CCTA for Stable Chest Pain**

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
</table>

CAD: coronary artery disease; CCTA: coronary computed tomographic angiography; NR: not reported; RCT: randomized controlled trial.

**Table 15. Results of Systematic Reviews Assessing CCTA for Stable Chest Pain**

<table>
<thead>
<tr>
<th>Study</th>
<th>Incidence of ICA, %</th>
<th>Revascularization, %</th>
<th>Adverse Events, %</th>
<th>New Diagnoses of CAD, %</th>
<th>Medication Use, %a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foy et al (2017)</td>
<td>11.7 vs 9.1</td>
<td>7.2 vs 9.1</td>
<td>Mortality: 1.0 vs 1.1</td>
<td>18.3 vs 8.3</td>
<td>Aspirin: 21.6 vs 8.2 Statins: 20.0 vs 7.3</td>
</tr>
<tr>
<td>CCTA vs Functional stress testing</td>
<td>1.33 (1.12 to 1.59)</td>
<td>1.86 (1.43 to 2.43)</td>
<td>Mortality: 0.93 (0.71 to 1.21) Hospitalization: 0.98 (0.79 to 1.21) MI: 0.71 (0.53 to 0.96)</td>
<td>2.80 (2.03 to 3.87)</td>
<td>Aspirin: 2.21 (1.21 to 4.04) Statins: 2.03 (1.09 to 3.76)</td>
</tr>
</tbody>
</table>

CAD: coronary artery disease; CCTA: coronary computed tomographic angiography; CI: confidence interval; ICA: invasive coronary angiography; MI: myocardial infarction; RR: relative risk.

**Randomized Controlled Trials**

For patients at intermediate risk of CAD, 3 major RCTs were identified by comparing outcomes after a CCTA strategy with outcomes after other noninvasive testing strategies. Tables 16 and 17 summarize trial characteristics and results.

**Table 16. Characteristics of Key RCTs Assessing CCTA in Stable Chest Pain**

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCOT-HEART Investigators</td>
<td>U.K.</td>
<td>12</td>
<td>2010-2014</td>
<td>Patients referred for assessment of suspected angina due to CHD</td>
<td>2073 to standard of care plus CCTA</td>
</tr>
</tbody>
</table>

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Douglas et al (2014) reported on the PROMISE trial, which randomized 10,003 patients to CCTA or exercise electrocardiography, nuclear stress testing, or stress echocardiography (as determined by physician preference) as the initial diagnostic evaluation. \(^{30}\) CCTA also did not meet prespecified noninferiority criteria compared with alternative testing. Some clinical outcomes assessed at 12 months favored CCTA, but the differences were nonsignificant. Coronary catheterization rates and revascularization rates were higher in the CCTA group. In a further prespecified analysis of PROMISE trial data, Hoffmann et al (2017) found that there was no difference in event rates (death, MI, or angina) between the groups at a median of 26 months follow-up. \(^{33}\) However, CCTA had better discriminatory ability than functional testing to predict events (e.g., in categories of normal, mildly abnormal, moderately abnormal, and severely abnormal) in patients who had nonobstructive CAD \((p=0.04)\). When the Framingham Risk Score was added to functional testing results, there was no significant difference in prognostic capability between the approaches \((p=0.29)\).

In the SCOT-HEART trial (2015), investigators randomized 4146 patients to CCTA plus SOC or SOC alone. The primary end point was the change in the proportion of patients with a more certain diagnosis (presence or absence) of angina pectoris. \(^{31}\) Secondary outcomes included death, MI, revascularization procedures, and hospitalizations for chest pain. Analysis of the primary outcome showed that patients who underwent CCTA had an increase in the certainty of their diagnosis relative to those in usual care \((relative\ risk, 1.79; 95\% CI, 1.62\ to\ 1.96)\). Williams et al (2017) reported on symptoms and quality of life for participants in the SCOT-HEART trial. \(^{34}\) Symptoms improved in both groups; however, improvements in symptoms and quality of life at 6 months were lower in patients in the CCTA arm than the functional testing arm. This outcome was due primarily to patients who were diagnosed with moderate CAD or had a new prescription of preventative therapy compared with patients diagnosed with normal coronary arteries or who had their preventative therapy discontinued.

In the CAPP trial, McKavanagh et al (2015) randomized 500 patients with stable chest pain to CCTA or exercise stress testing. \(^{32}\) The primary outcome was the change difference in scores of Seattle Angina Questionnaire domains at 3 months. Patients were also followed for further diagnostic tests and management. In the CCTA arm, 15.2% of subjects underwent revascularization. In the exercise stress testing arm, 7.7% underwent revascularization. For the primary outcome, angina stability and quality of life showed significantly greater improvement in the CCTA arm than in the exercise stress testing arm.

**Table 17. Results of Key RCTs Assessing CCTA in Stable Chest Pain**

<table>
<thead>
<tr>
<th>Study</th>
<th>Death or Nonfatal Myocardial Infarction</th>
<th>Angina Stability</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Douglas et al (2015) (^{30})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCTA group</td>
<td>104</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Functional testing group</td>
<td>112</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.88 (0.67 to 1.15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(p)</td>
<td>0.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCOT-HEART Investigators (2015) (^{31})</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCTA, n (%)</td>
<td>26</td>
<td>511 (12.3)</td>
<td></td>
</tr>
<tr>
<td>Standard care, n (%)</td>
<td>42</td>
<td>247 (11.9)</td>
<td></td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.616 (0.378 to 1.006)</td>
<td>0.928 (0.780 to 1.104)</td>
<td></td>
</tr>
<tr>
<td>(p)</td>
<td>0.527</td>
<td>0.399</td>
<td></td>
</tr>
</tbody>
</table>
Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation

### Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Death or Nonfatal Myocardial Infarction</th>
<th>Angina Stability</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD at 3 mo (95% CI)</td>
<td>-11.1 (-17.4 to -4.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MD at 12 mo (95% CI)</td>
<td>-6.8 (-12.8 to -0.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p</td>
<td></td>
<td></td>
<td>0.028</td>
</tr>
</tbody>
</table>

CI: confidence interval; CCTA: coronary computed tomographic angiography; HR: hazard ratio; MD: mean difference; RCT: randomized controlled trial.

Tables 18 and 19 display notable the gaps identified in each trial.

#### Table 18. Relevance Gaps of RCTs Assessing CCTA in Stable Chest Pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCOT-HEART Investigators (2015)³¹</td>
<td>4. Patients &gt;75 y excluded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McKavanagh et al (2015)³²</td>
<td>4. Low number of diabetics included due to exclusion criteria</td>
<td>1. Noted difficulty in contrasting the results of anatomic and functional tests</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

CCTA: coronary computed tomographic angiography; RCT: randomized controlled trial.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

c Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.

d Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).

e Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

#### Table 19. Study Design and Conduct Gaps of RCTs Assessing CCTA for Stable Chest Pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Selection</th>
<th>Blinding</th>
<th>Delivery of Test</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Douglas et al (2015)³⁰</td>
<td>1.-3. Treatments and outcomes not blinded and potential bias among attending clinicians was present</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCOT-HEART Investigators (2015)³¹</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McKavanagh et al (2015)³²</td>
<td>3. Study not powered to evaluate prognosis or adverse CAD events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CAD: coronary artery disease; CCTA: coronary computed tomographic angiography; RCT: randomized controlled trial.

a Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
b Blinding key: 1. Not blinded to results of reference or other comparator tests.
c Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
e Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
f Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison to other tests not reported.

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

Nielsen et al (2013) conducted an observational trial comparing patients who underwent CCTA with those having exercise stress testing.35 Patients had a low-to-intermediate pretest probability of CAD and presented with suspected angina. Patients were followed for 12 months after the initial test and assessed for occurrence of major adverse events (e.g., cardiac death, nonfatal MI). Subsequent utilization of cardiovascular tests and therapy were also compared between groups. Clinical outcomes were not formally compared because there were few clinical events. No deaths were reported during the follow-up period. Three patients in the exercise testing group had MIs within 12 months. For downstream test utilization, the exercise test group had greater subsequent use of perfusion imaging (9% vs 4%, p=0.03). Rates of ICA and revascularization did not differ significantly between groups.

In 2825 patients evaluated for stable angina and suspected CAD in Japan, Yamauchi et al (2012) examined outcomes after initial CCTA (n=625), MPI (n=1205), and angiography (n=950).36 Average follow-up was 1.4 years. In a Cox proportional hazards model adjusted for potential confounders, the relative hazard rates of major cardiac events after MPI or CCTA were lower than after angiography; annual rates were 2.6%, 2.1%, and 7.0%, respectively. Revascularization rates were higher after CCTA than MPI (OR=1.6; 95% CI, 1.2 to 2.2).

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

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

The nonrandomized studies of CCTA have several methodologic shortcomings, including reliance on administrative data and inability to assess and adjust fully for potential confounding. The findings have shown little difference in patient outcomes between diagnostic strategies. Downstream utilization of medical care showed variable findings.

**Suspected Anomalous Coronary Arteries**

Anomalous coronary arteries are an uncommon finding during angiography, occurring in approximately 1% of coronary angiograms completed for evaluation of chest pain. However, these congenital anomalies can be clinically important depending on the course of the anomalous arteries. A number of case series have consistently reported that CCTA can delineate the course of these anomalous arteries, even when conventional angiography cannot. However, none of the studies reported results when the initial reason for the study was to identify these anomalies, nor did any of the studies discuss the impact on therapeutic decisions. Given the uncommon occurrence of these symptomatic anomalies, it is unlikely that a prospective trial of CCTA could be completed.

**Clinical Context and Therapy Purpose**

The purpose of CCTA in patients who have suspected anomalous coronary arteries is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of CCTA improve net health outcomes in patients with suspected anomalous coronary arteries?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest is individuals with suspected anomalous coronary arteries.

**Interventions**

The therapy being considered is CCTA.

**Comparators**

The following practice is currently being used to make decisions about managing suspected anomalous coronary arteries: SOC without CCTA.

**Outcomes**

The general outcomes of interest are overall survival, test accuracy, morbid events, and resource utilization.

**Timing**

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

**Setting**

CCTA is administered in cardiology clinic setting equipped with standard noninvasive testing for CAD and CCTA.

**Technically Reliable**

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and
unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**Clinically Valid**
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

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

Exposure to ionizing radiation increases lifetime cancer risk. Three studies have estimated excess cancer risks due to radiation exposure from CCTA. Assuming a 16-mSv dose, Berrington de Gonzalez et al (2009) estimated the 2.6 million CCTAs performed in 2007 would result in 2700 cancers or approximately 1 per 1000. Smith-Bindman et al (2009) estimated that cancer would develop in 1 of 270 women and 1 of 600 men age 40 undergoing CCTA with a 22-mSv dose. Einstein et al (2007) employed a standardized phantom to estimate organ dose from 64-slice CCTA. With modulation and exposures of 15 mSv in men and 19 mSv in women, calculated lifetime cancer risk at age 40 was 7 per 1000 men (1/143) and 23 per 1000 women (1/43). However, estimated radiation exposure used in these studies was considerably higher than received with current scanners—now typically under 10 mSv and often less than 5 mSv with contemporary machines and radiation reduction techniques. For example, in the 47-center PROTECTION I study enrolling 685 patients, the mean radiation dose was 3.6 mSv, using a sequential scanning technique. In a study of patients undergoing an axial scanning protocol, Hausleiter et al (2012) reported on mean radiation dose of 3.5 mSv, and produced equivalent ratings of image quality compared with helical scan protocols, which had much higher mean radiation doses of 11.2 mSv.

**Clinically Useful**
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

**Direct Evidence**
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No RCTs were identified assessing the clinical utility of CCTA for suspected anomalous coronary arteries.

**Chain of Evidence**
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the clinical validity of CCTA for suspected anomalous coronary arteries has not been established, a chain of evidence cannot be constructed.

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

Given its ability to define coronary artery anatomy, there are many potential diagnostic uses of CCTA, including patency of coronary artery bypass grafts, in-stent restenosis, screening, and preoperative evaluation.

Patency

Evaluating patency of vein grafts is less technically challenging due to vein size and lesser motion during imaging. In contrast, internal mammary grafts may be more difficult to image due to their small size and presence of surgical clips. Finally, assessing native vessels distal to grafts presents difficulties, especially when calcifications are present, due to their small size. For example, a systematic review, including results from 64-slice scanners, Stein et al (2008) reported high sensitivity (98%; 95% CI, 95% to 99%; 740 segments) and specificity (97%; 95% CI, 94% to 97%). Other small studies have reported high sensitivity and specificity. Lacking are multicenter studies demonstrating likely clinical benefit, particularly given the reasonably high disease prevalence in patients evaluated.

In-Stent Restenosis

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

Screening

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

Preoperative Evaluation

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

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

Summary of Evidence

For individuals who have acute chest pain and suspected coronary artery disease in the emergency setting, at intermediate to low risk, who receive CCTA, the evidence includes several randomized controlled trials, a systematic review, and a prospective head-to-head study comparing CCTA with an alternative noninvasive test. Relevant outcomes are overall survival, morbid events, and resource utilization. Trials have shown similar patient outcomes, with faster patient discharges from the emergency department, and lower short-term costs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

Supplemental Information
Practice Guidelines and Position Statements

American College of Cardiology Foundation et al
The American College of Cardiology Foundation and several other medical societies (2012) issued joint guidelines for management of patients with stable ischemic heart disease (see Table 20).

Table 20. Guidelines on Management of Stable IHD

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Recommendation</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unknown</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to exercise</td>
<td>“CCTA might be reasonable for patients with an intermediate pretest probability of IHD who have at least moderate physical functioning or no disabling comorbidity.”</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>“CCTA is reasonable for patients with a low-to-intermediate pretest probability of IHD who are incapable of at least moderate physical functioning or have disabling comorbidity.”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>“CCTA is reasonable for patients with an intermediate pretest probability of IHD who a) have continued symptoms with prior normal test findings, or b) have inconclusive results from prior exercise or pharmacological stress testing, or c) are unable to undergo stress with nuclear MPI or echocardiography.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td><strong>Known coronary disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Able to exercise</td>
<td>“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.”</td>
<td>IIb</td>
<td>B</td>
</tr>
<tr>
<td>Able to exercise</td>
<td>“Pharmacological stress imaging (nuclear MPI, echocardiography, or CMR) or CCTA is not recommended for risk assessment in patients with SIHD who are able to exercise to an adequate workload and have an interpretable ECG.”</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>“Pharmacological stress CMR is reasonable for risk assessment in patients with SIHD who are unable to exercise to an adequate workload regardless of interpretability of ECG.”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>“CCTA can be useful as a first-line test for risk assessment in patients with SIHD who are unable to exercise to an adequate workload regardless of interpretability of ECG.”</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Unable to exercise</td>
<td>“A request to perform either a) more than 1 stress imaging study or b) a stress imaging study and a CCTA at the same time is not recommended for risk assessment in patients with SIHD.”</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>Regardless of patients' ability to exercise</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation

**Diagnosis**

“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.”

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Recommendation</th>
<th>Class</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“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.”</td>
<td>llb</td>
<td>C</td>
</tr>
</tbody>
</table>

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

The American College of Cardiology Foundation and other medical societies (2013) published appropriate use criteria for detection and risk assessment of stable ischemic heart disease.59 Coronary computed tomography angiography (CCTA) was considered appropriate for:

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

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2016) has recommended CCTA as first-line testing for patients with stable angina if the clinical assessment indicates typical or atypical angina, or if the clinical assessment indicates nonanginal chest pain but 12-lead resting ECG has been done and indicates ST-T changes or Q waves.60

**U.S. Preventive Services Task Force Recommendations**

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

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 21.

**Table 21. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT Number</th>
<th>Title</th>
<th>Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Computed Tomography Coronary Angiography for Heart Failure Patients (CCTA – HF) Project I-C of Imaging Modalities to Assist With Guiding Therapy and the Evaluation of Patients With Heart Failure (IMAGE-HF)</td>
<td>253</td>
<td>Dec 2018</td>
</tr>
<tr>
<td></td>
<td>Diagnostic Imaging Strategies for Patients With Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies - A Pragmatic Randomised Controlled Trial of CT Versus ICA</td>
<td>3546</td>
<td>Sep 2019</td>
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<td></td>
<td>The Role of Early CT Coronary Angiography in the Evaluation, Intervention and Outcome of Patients Presenting to the Emergency Department With Suspected or Confirmed Acute Coronary Syndrome</td>
<td>2500</td>
<td>Dec 2019</td>
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<tr>
<td>Unpublished</td>
<td>Comprehensive Cardiac CT Versus Exercise Testing in Suspected Coronary Artery Disease (2) (CRESCENT2)</td>
<td>250</td>
<td>May 2016 (completed)</td>
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<tr>
<td></td>
<td>A Randomized Trial Comparing Coronary CT Angiography and Stress Echocardiography for Evaluation of Low-to-Intermediate Risk Emergency Department Chest Pain Patients</td>
<td>400</td>
<td>Feb 2017 (completed)</td>
</tr>
</tbody>
</table>
Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation

### NCT Number | Title | Enrollment | Completion Date
--- | --- | --- | ---
NCT01559467 | The Supplementary Role of Non-invasive Imaging to Routine Clinical Practice in Suspected Non-ST-elevation Myocardial Infarction (CARMENTA) | 300 | June 2017 (completed)

NCT: national clinical trial.

### References


coronary syndrome chest pain in the emergency department (CT-COMPARE). Int J Cardiol. Dec 20 2014;177(3):867-873. PMID 25466568


Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Current symptoms and clinical findings
  - Reason for the procedure
- Diagnostic radiology reports pertaining to request (e.g., echocardiogram, transesophageal echocardiogram, MRI)
Post Service
- Radiology procedure report(s)

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>75574</td>
<td>Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>B221Y0Z</td>
<td>Computerized Tomography (CT Scan) of Multiple Coronary Arteries using Other Contrast, Unenhanced and Enhanced</td>
</tr>
</tbody>
</table>

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/03/2009</td>
<td>Policy Name Change Combined:</td>
<td>Medical Policy Committee</td>
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<tr>
<td></td>
<td>Electron Beam Computed Tomography (EBCT) for Detection and Evaluation of Coronary Artery Calcium Measurement</td>
<td></td>
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<tr>
<td></td>
<td>Contrast-Enhanced Computed Tomography Angiography (CTA) for Coronary Artery Evaluation</td>
<td></td>
</tr>
<tr>
<td>01/15/2010</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>01/06/2012</td>
<td>Policy title change from Cardiac Computed Tomography with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>07/31/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>02/01/2017</td>
<td>Policy title change from Cardiac Computed Tomography (CT) and Coronary CT Angiography</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td></td>
<td>Policy revision without position change</td>
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<tr>
<td></td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>11/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/01/2018</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>
**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state government is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.