

Policy # 00153

Original Effective Date: 07/15/2005 Current Effective Date: 10/20/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Noninvasive Fractional Flow Reserve Using Computed Tomography Angiography is addressed in medical policy 00537.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the use of contrast-enhanced coronary computed tomography angiography (CCTA) for coronary artery evaluation to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for **ANY** of the following conditions:

- For evaluation of suspected congenital anomalies of the coronary arteries in **ANY** of the following scenarios:
 - o Exertional syncope; **OR**
 - o History of anomalous coronary artery in a first-degree relative; OR
 - o Following coronary angiography which failed to adequately define the origin or course of a coronary artery; **OR**
 - o Coronary ostia appear to be abnormally positioned on echocardiography;

OR

Evaluation of individuals with acute chest pain and without known coronary artery disease

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(CAD) in the emergency department (ED) setting; **OR**

- Suspected coronary artery disease (CAD) in symptomatic patients who <u>have not</u> had evaluation for CAD (e.g., MPI, stress echo, cardiac perfusion PET, stress MRI, CCTA, or coronary angiography) within the preceding 60 days in **ANY** of the following scenarios (See Policy Guidelines):
 - Chest pain or dyspnea (with or without other symptoms of myocardial ischemia) with pretest probability of CAD > 15% (see Table 1); **OR**
 - Patients with any cardiac symptoms who have disease/condition with which CAD commonly coexists, i.e., abdominal aortic aneurysm, established and symptomatic peripheral vascular disease, history of stroke, transient ischemic attack (TIA), carotid endarterectomy (CEA), high-grade carotid stenosis (> 70%), or chronic kidney disease;

OR

- Established flow-limiting coronary artery disease (CAD) in patients who have new or worsening symptoms despite maximal anti-ischemic medical therapy (see Policy Guidelines) or contraindication thereto; **OR**
- Patients who have undergone cardiac transplantation and have new or worsening cardiac symptoms, physical examination abnormalities, or are clinically stable and have not had evaluation for CAD in the preceding year; **OR**
- Patients (symptomatic or asymptomatic) with new onset arrhythmias who have not had evaluation for CAD since the arrhythmia was recognized in **ANY** of the following scenarios:
 - O Sustained (lasting more than 30 seconds) or nonsustained (more than 3 beats but terminating within 30 seconds) ventricular tachycardia; **OR**
 - Atrial fibrillation or flutter and high or intermediate risk of CAD (using ASCVD Pooled Cohort Equation); OR
 - o Atrial fibrillation or flutter and established CAD; **OR**
 - Frequent premature ventricular contractions (PVCs) defined as more than 30 PVCs per hour on ambulatory EKG (Holter) monitoring;

OR

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- Patients (symptomatic or asymptomatic) with new onset congestive heart failure (CHF) or recently recognized LV systolic dysfunction who have not had evaluation for CAD since the onset of LV dysfunction/CHF; OR
- Patients with **ANY** of the following newly recognized and not previously evaluated resting EKG changes:
 - o Left bundle branch block (LBBB); **OR**
 - o ST depression > 1 mm; **OR**
 - o Left ventricular hypertrophy (LVH) with repolarization abnormality;

OR

- Patients with established or suspected CAD who would otherwise undergo exercise EKG testing (without imaging) but have **ANY** of the following resting EKG findings that would render the interpretation of an exercise EKG test difficult or impossible:
 - o LBBB; OR
 - Ventricular paced rhythm; **OR**
 - o LVH with repolarization abnormality; **OR**
 - o Digoxin effect; **OR**
 - o ST depression > 1 mm on a recent EKG (within the past 30 days); **OR**
 - o Pre-excitation syndromes (e.g., Wolff-Parkinson-White syndrome);

OR

- Patients with established or suspected CAD who would otherwise undergo exercise EKG testing (without imaging) but are unable for reasons other than obesity (including patients with musculoskeletal, neurological or pulmonary limitations) to perform exercise to a degree that would yield a diagnostic test; **OR**
- Patients with abnormal exercise treadmill test (performed without imaging) who have not undergone evaluation for CAD since the treadmill test
 - o Abnormal findings on an exercise treadmill test include chest pain, ST segment change, abnormal blood pressure response, or complex ventricular arrhythmia;

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OR

- Patients who have undergone stress testing with imaging (MPI, stress echo, cardiac perfusion PET, stress MRI) within the past 60 days and **ONE** of the following is met:
 - When the stress imaging test is technically suboptimal, technically limited, inconclusive, indeterminate, or equivocal, such that myocardial ischemia cannot be adequately excluded.
 - A stress imaging test is considered abnormal when there are abnormalities on the imaging portion of the test. Electrocardiographic abnormalities without imaging evidence of ischemia do not render a stress imaging test abnormal;

OR

- When the stress imaging test is abnormal, and **ALL** of the following are met:
 - The stress test demonstrates moderate or severe ischemia; AND
 - cCTA is requested to exclude left main CAD; AND
 - In the absence of left main CAD, guideline directed medical treatment (GDMT) will be instituted; **AND**
 - Invasive coronary angiography will be reserved for persistent symptoms on GDMT;

OR

- Preoperative cardiac evaluation of patients undergoing non-coronary cardiac surgery in ANY
 of the following scenarios:
 - o Patients undergoing evaluation for transcatheter aortic valve implantation/replacement (TAVI or TAVR) at low risk for CAD (using ASCVD Pooled Cohort Equations) to avoid invasive angiography, where all the necessary preoperative information can be obtained using cardiac CT; **OR**
 - o Patients undergoing evaluation for valve surgery (other than TAVR) at low or intermediate risk for CAD (using ASCVD Pooled Cohort Equations);

OR

• Preoperative cardiac evaluation of patients undergoing non-cardiac elective surgery,

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including surveillance for CAD for patients awaiting solid organ transplant in **ANY** of the following scenarios:

- Patients with active cardiac conditions, e.g., unstable angina, decompensated heart failure NYHA class IV, new onset heart failure, significant arrhythmia (third degree AV block, Mobitz II AV block, uncontrolled supraventricular or ventricular arrythmia, ventricular tachycardia, symptomatic bradycardia), or severe stenotic valvular lesions would be evaluated and managed per ACC/AHA guidelines prior to considering elective surgery (evaluation may include CCTA); OR
- Prior to intermediate-risk surgery (e.g., intraperitoneal and intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery, prostate surgery, gastric bypass surgery) or high-risk surgery (e.g., aortic and other major vascular surgery, peripheral vascular surgery) when **BOTH** of the following are met:
 - Patient has not had a negative evaluation for CAD or coronary revascularization procedure within the previous one year; AND
 - At least ONE of the following applies:
 - Patient has established CAD (prior MI, PCI or CABG) or presumed CAD (Q waves on EKG, abnormal MPI, stress echo, or cardiac PET);
 OR
 - ❖ Patient has compensated heart failure or prior history of CHF; **OR**
 - ❖ Patient has diabetes mellitus; **OR**
 - ❖ Patient has chronic kidney disease; **OR**
 - ❖ Patient has a history of cerebrovascular disease (TIA, stroke, or history of carotid endarterectomy; **OR**
 - ❖ Patient is unable to walk on a treadmill for reasons other than obesity:

OR

- o Patients awaiting solid organ transplant in **ANY** of the following scenarios:
 - Asymptomatic patient who have not undergone evaluation for CAD within the preceding one year; **OR**
 - Symptoms consistent with myocardial ischemia;

OR

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- Patients with Kawasaki disease in **ANY** of the following scenarios:
 - Periodic surveillance up to one year following diagnosis of Kawasaki disease when previous imaging study reveals ANY of the following:
 - Coronary abnormalities; OR
 - Left ventricular dysfunction; OR
 - Pericardial effusion; **OR**
 - Valvular regurgitation (other than trace or trivial); OR
 - Aortic dilation;

OR

- Annual evaluation in patients who have small or medium-sized coronary artery aneurysm; **OR**
- Semiannual evaluation (every 6 months) in patients who have large or giant coronary artery aneurysm, or coronary artery obstruction.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers contrast-enhanced coronary computed tomography angiography (CCTA) for preoperative cardiac evaluation prior to low-risk surgery (i.e., endoscopic procedures, superficial procedures, cataract surgery, breast surgery, ambulatory surgery), provided there are no active cardiac conditions outlined above, to be **investigational***.

Based on review of available data, the Company considers contrast-enhanced coronary computed tomography angiography (CCTA) for coronary artery evaluation to be **investigational*** for all other indications.

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Policy Guidelines

Although chest pain is the most common symptom associated with myocardial ischemia, pain in other locations (epigastrium, back, neck, jaw, arm) should prompt consideration of myocardial ischemia. Therefore, the term "chest pain" when used in this policy includes pain in these locations.

Established flow-limiting CAD represents CAD which limits downstream blood flow as evidenced by **ANY** of the following:

- Abnormal stress imaging test; **OR**
- Coronary angiography (CCTA or invasive) demonstrating significant coronary stenosis (> 70% non-left or > 50% left main); **OR**
- Fractional flow reserve (FFR) < or = 0.8 or iFR < or = 0.89; **OR**
- History of myocardial infarction, percutaneous coronary intervention (PCI) or CABG.

Pretest Probability and CAD Risk Assessment

Reliability of noninvasive testing in accurately diagnosing or excluding CAD is dependent upon the likelihood of disease, which takes into account both pretest probability and atherosclerotic disease risk.

In those with low likelihood of disease, there is an unacceptably high rate of false-positive results, thus rendering these tests unreliable and potentially harmful.

Pretest probability may be estimated based on the quality of symptoms, age, and gender.

- Cardiac chest pain is centrally located, provoked by stress (exercise or emotional), and relieved by rest
- Possible cardiac chest pain has two of the three characteristics associated with cardiac chest pain
- Non-cardiac chest pain has one (or none) of the three characteristics associated with cardiac chest pain

Table 1 below shows the pretest probability of obstructive CAD for patients presenting with chest pain and dyspnea stratified by age, gender, and the nature of the symptoms.

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Table 1. Pretest Probability (%) of Coronary Artery Disease by Age, Gender, and Symptoms								
	Car	diac	Possible (cardiac	Nonca	rdiac	Dyspn	ıea [#]
Age (years)	Male	Female	Male	Female	Male	Female	Male	Female
<u>30-39</u>	<u>3</u>	<u>5</u>	<u>4</u>	<u>3</u>	<u>1</u>	<u>1</u>	0	<u>3</u>
40-49	<u>22</u>	<u>10</u>	<u>10</u>	<u>6</u>	3	2	<u>12</u>	<u>3</u>
<u>50-59</u>	<u>32</u>	<u>13</u>	<u>17</u>	<u>6</u>	<u>11</u>	<u>3</u>	<u>20</u>	9
60-69	<u>44</u>	<u>16</u>	<u>26</u>	<u>11</u>	22	<u>6</u>	<u>27</u>	<u>14</u>
<u>70+</u>	<u>52</u>	27	<u>34</u>	<u>19</u>	24	<u>10</u>	32	<u>12</u>

[#]Applies to patients who have dyspnea without chest pain.

Adapted from Knuuti J, Wijns W, Saraste A, et al. 2019 ESC guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. 2020;41: 407–477.

Atherosclerotic disease risk

The atherosclerotic cardiovascular disease (ASCVD) pooled cohort equations risk calculation tool is used to estimate risk of atherosclerotic cardiovascular disease. This tool, which is endorsed by several professional societies, incorporates age, gender, race, several clinical conditions known to affect ASCVD risk (including diabetes, dyslipidemia, hypertension), and tobacco use.

Guideline-directed medical therapy (GDMT) consists of risk factor management and, in symptomatic patients, antianginal medications which improve quality of life. Risk factor management:

All patients with stable CAD should be encouraged to adopt healthy lifestyles including tobacco cessation/avoidance, regular physical activity, maintenance of a healthy weight and adherence to a healthy diet. In addition, absent a contraindication, all stable CAD patients should be taking the following evidence-supported medications:

- Antiplatelet agents Aspirin and/or P2Y12 receptor antagonist
- Statin Maximum tolerated dose of high-intensity statin (atorvastatin 40-80 mg or

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rosuvastatin 20-40 mg). Patients intolerant of statins and/or not reaching LDL cholesterol goal on maximum tolerated statin dose should be treated with ezetimibe, a PCSK9 inhibitor, or bempedoic acid.

- Beta blockers In patients with a history of myocardial infarction, who have left ventricular systolic dysfunction (ejection fraction ≤ 40%), or as an option for management of hypertension.
- ACE Inhibitor or Angiotensin Receptor Blocker In patients with left ventricular systolic dysfunction (ejection fraction ≤ 40%), diabetes, chronic kidney disease, or as an option for management of hypertension
- Antidiabetic agents For patients who are diabetic (Hemoglobin A1c goal should be < 8% in all patients although more aggressive management may be appropriate for some)

Symptom control:

Most patients with stable CAD who have symptoms should be offered anti anginal medications as an initial approach with revascularization reserved for those who have persistent unacceptable symptoms despite maximally tolerated doses.

- Beta blockers Unless contraindicated beta blockers are first-line therapy with dose escalation until symptoms resolve or side effects develop.
- Calcium channel blockers and/or long acting-nitrates should be used as alternative initial
 therapy in symptomatic patients who have contraindication to, or intolerance of, beta
 blockers. They should also be prescribed when symptoms persist despite maximum tolerated
 doses of beta blockers.
- Ranolazine may be prescribed either as initial therapy in symptomatic patients who have contraindication to, or intolerance of, other antianginal medication, or for those with persistent symptoms despite treatment with other medications as described above.

Background/Overview

Coronary Artery Disease

Various noninvasive tests are used to diagnose coronary artery disease (CAD). These tests 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

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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 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 (ie, 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.

The use of electron-beam computed tomography or helical computed tomography to detect coronary artery calcification and the use of fractional flow reserve computed tomography to support the functional evaluation of CAD are addressed separately in medical policies 00031 and 00537, respectively.

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Coronary Arterial Anomalies

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

Radiation Exposure

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 scannersnow typically under 10 mSv and often less than 5 mSv with contemporary machines and radiation reduction techniques. For example, in the 47-center Prospective Multicenter Study on Radiation Dose Estimates of Cardiac CT Angiography I (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 a 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.

Levels of radiation delivered with the 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 to 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

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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 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 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.

Incidental Findings

A number of studies using scanners with 64 or more detector rows were identified. Incidental findings were frequent (26.6% to 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% versus 24% when the entire field was imaged).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Description

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 is a potential diagnostic alternative to current tests for cardiac ischemia (ie, noninvasive stress testing and/or coronary angiography).

Summary of Evidence

For individuals who have acute chest pain and suspected coronary artery disease (CAD) in the emergency setting, at intermediate- to low-risk, who receive coronary computed tomography angiography (CCTA), the evidence includes several randomized controlled trials (RCTs), 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 an improvement in the net health outcome.

For individuals who have stable chest pain, intermediate-risk of CAD, and meeting guideline criteria for noninvasive testing (ie, 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 systematic reviews. Relevant outcomes are overall survival, test accuracy, morbid events, and resource utilization. Studies of diagnostic accuracy have shown that CCTA has higher sensitivity and similar specificity to alternative noninvasive tests. Although randomized trials have not shown the superiority of CCTA over other diagnostic strategies, results are consistent with noninferiority (ie, similar health outcomes) to other diagnostic strategies. The evidence is sufficient to determine that the technology results in an 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

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patient management will be affected by CCTA results (eg, 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 an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology Foundation et al

The American College of Cardiology along with several other organizations (2021) published guidelines for evaluation and diagnosis of chest pain that include recommendations for coronary computed tomography angiography (CCTA).

For intermediate-risk patients with no known coronary artery disease (CAD) the guidelines pertinent to CCTA state:

- "For intermediate-risk patients with acute chest pain and no known CAD eligible for diagnostic testing after a negative or inconclusive evaluation for ACS [acute coronary syndrome], CCTA is useful for exclusion of atherosclerotic plaque and obstructive CAD."
- "For intermediate-risk patients with acute chest pain with evidence of previous mildly abnormal stress test results (≤1 year), CCTA is reasonable for diagnosing obstructive CAD."
- "For intermediate-risk patients with acute chest pain and no known CAD, as well as an
 inconclusive prior stress test, CCTA can be useful for excluding the presence of
 atherosclerotic plaque and obstructive CAD."

For intermediate-risk patients with known CAD the guidelines pertinent to CCTA state:

• "For intermediate-risk patients with acute chest pain and known nonobstructive CAD, CCTA can be useful to determine progression of atherosclerotic plaque and obstructive CAD."

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The American College of Cardiology Foundation and several other medical societies (2012) issued joint guidelines for the management of patients with stable ischemic heart disease (Table 2).

Table 2. Guidelines on Management of Stable IHD

Diagnosis	Recommendation	Class	LOE
Unknown			
	Able to exercise		
	"CCTA might be reasonable for patients with an intermediate pretest probability of IHD who have at least moderate physical functioning or no disabling comorbidity."	IIb	В
	Unable to exercise		
	"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 a disabling comorbidity."	IIa	В
	"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."	IIa	С
Known coronary disease			
	Able to exercise		
	"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."	IIb	В

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Diagnosis	Recommendation	Class	LOE
	"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."	III	С
	Unable to exercise		
	"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."	IIa	В
	"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."	IIa	С
	"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."	III	С
	Regardless of patients' ability to exercise		
	"CCTA might be considered for risk assessment in patients with SIHD unable to undergo stress imaging or as an alternative to invasive coronary angiography when functional testing indicates a moderate- to high-risk result and knowledge of angiographic coronary anatomy is unknown."	IIb	С

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. Coronary computed tomography angiography (CCTA) was considered appropriate for:

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- Symptomatic patients with intermediate (10% to 90%) pretest probability of coronary artery disease (CAD) 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 non anginal chest pain but 12-lead resting electrogardiography (ECG) has been done and indicates ST-T changes or Q waves.

Society of Cardiovascular Computed Tomography

The Society of Cardiovascular Computed Tomography (SCCT, 2021) published an expert consensus document on CCTA. Recommendations on use of CCTA in select patients are included in Table 3. In addition to the recommendations listed below, the expert consensus included additional recommendations in several patient populations, including patients with known CAD.

Table 3. Society of Cardiovascular Computed Tomography Guidelines on Coronary Computed Tomography Angiography

Diagnosis	Recommendation
Stable chest pain with no known CAD	It is appropriate to perform CTA as the first line test for evaluating patients with no known CAD who present with stable typical or atypical chest pain, or other symptoms which are thought to represent a possible anginal equivalent (eg, dyspnea on exertion, jaw pain).
	It is appropriate to perform coronary CTA following a nonconclusive functional test, in order to obtain more precision regarding

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	diagnosis and prognosis, if such information will influence subsequent patient management.
	Coronary CTA is rarely appropriate in very low risk symptomatic patients, such as those <40 years of age who have noncardiac symptoms (eg, chest wall pain, pleuritic chest pain).
Noncardiac surgery	It is appropriate to perform CTA as an alternative to other noninvasive tests for evaluation of selected patients prior to noncardiac surgery.
Coronary anomalies	It is appropriate to perform CTA for the evaluation of coronary anomalies.

CAD: coronary artery disease; CTA: cardiac computed tomography angiography.

In 2022, SCCT published an expert consensus document on use of CCTA for patients presenting to the emergency department with acute chest pain. Relevant recommendations from the consensus document are listed in Table 3.

Table 3. Society of Cardiovascular Computed Tomography Guidelines on Coronary Computed Tomography Angiography for Acute Chest Pain in the Emergency Department

Scenario	Recommendation
Patient with no known CAD	
ECG diagnostic for STEMI	CCTA is usually not appropriate (door-to-balloon time <90 minutes should be prioritized).
NSTE-ACS is leading diagnosis (evidence of myocardial ischemia on ECG without ST-segment elevation, elevated troponin)	CCTA may be appropriate (eg, to determine if invasive evaluation is appropriate).

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High risk for ACS (no definite evidence of myocardial ischemia on ECG, normal or equivocal troponin)	CCTA may be appropriate as an alternative to functional testing or invasive evaluation.
Low to intermediate risk for ACS (no definite evidence of myocardial ischemia on ECG, normal or equivocal troponin, and/or inadequate or mildly abnormal functional testing during index ED visit or within previous year)	CCTA is appropriate and is most effective to rule out ACS.
Very low risk for ACS (no definite evidence of myocardial ischemia on ECG, normal or equivocal troponin, and/or non-cardiac chest pain is leading diagnosis)	CCTA may be appropriate (eg, to confidently exclude CAD and provide risk stratification).
Patient with documented CAD, post-revascularization	
Prior PCI with stent ≥3 mm within a proximal coronary segment (no definite evidence of myocardial ischemia on ECG, normal or equivocal troponin)	CCTA is appropriate for early triage.
Prior CABG (no definite evidence of myocardial ischemia on ECG, normal or equivocal troponin)	

ACS: acute coronary syndrome; CABG: coronary artery bypass grafting; CAD: coronary artery disease; CCTA: coronary computed tomography angiography; ECG: electrocardiography; ED: emergency department; NSTEMI: non-ST-segment-elevation myocardial infarction; ST-segment-elevation myocardial infarction.

U.S. Preventive Services Task Force Recommendations

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

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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 ongoing trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT Number	Title	Enrollment	Completion Date
Ongoing			
NCT04748237	Randomized Evaluation of Coronary Computed Tomographic Angiography in Intermediate-risk Patients Presenting to the Emergency Department With Chest Pain	3500	Dec 2025
NCT02099019	Usefulness of Coronary Computed Tomography Angiography for Therapeutic Decision-Making; Revascularization	3000	Feb 2025
NCT05677386	Prevention of Heart Disease in Adult Danes Using Computed Tomography Coronary Angiography - The DANE-HEART Trial	6000	Dec 2026
Unpublished			
NCT03129659	Coronary CT Angiography for Improved Assessment of Suspected Acute Coronary Syndrome With Inconclusive Diagnostic Work-up	230	Sep 2022

NCT: national clinical trial.

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expert consensus document of the Society of cardiovascular computed tomography (SCCT): Endorsed by the American College of Radiology (ACR) and North American Society for cardiovascular Imaging (NASCI). J Cardiovasc Comput Tomogr. 2023; 17(2): 146-163. PMID 36253281

Policy History

1 Officy This	<u>101 y</u>
Original Effecti	ve Date: 07/15/2005
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06/07/2005	Medical Director review
06/21/2005	Medical Policy Committee review
07/15/2005	Managed Care Advisory Council approval
07/07/2006	Format revision including addition of FDA and or other governmental regulatory
	approval and Rationale/source. Coverage eligibility unchanged.
09/06/2006	Medical Director review
12/06/2006	Medical Director review
12/20/2006	Medical Policy Committee approval. Coverage eligibility unchanged
01/09/2008	Medical Director review
01/23/2008	Medical Policy Committee approval. Eligible for coverage statement added for
	CTA evaluation of anomalous (native) coronary arteries in symptomatic patients
	when conventional angiography is unsuccessful or equivocal and when the results
	will impact treatment.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. No change to coverage eligibility.
01/01/2010	Coding revision
06/03/2010	Medical Policy Committee approval
06/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
11/03/2011	Medical Policy Committee review

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11/16/2011	Medical Policy Implementation Committee approval. Added coverage for evaluation of patients in the emergency room without known coronary artery disease and acute chest pain.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Replaced the 1st eligible for coverage criteria bullet to match the one from the 2008 policy. Added four new criteria bullets to be eligible for coverage. Included examples of standard methods of risk assessment such as Framingham or ACC criteria in the Patient Selection Criteria of this policy. Added a table to the Background/Overview section on the determination of pretest probability for coronary artery disease.
07/10/2014	
	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Added bullet point with AIM guidelines to patient selection criteria.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated background, rationale and references added "coronary" to title
	and policy statement.
02/01/2019	Medical Policy Committee review

03/01/2018 Medical Policy Committee review

Medical Policy Implementation Committee approval. Removed "when conventional angiography is unsuccessful or equivocal" from the first eligible for coverage criteria bullet. Added "acute" to describe chest pain in the second eligible for coverage criteria bullet. Removed the last eligible for coverage criteria bullet and replaced it with:

"To evaluate patients with suspected stable ischemic heart disease with at least intermediate risk (using standard methods of risk assessment such as Framingham or American College of Cardiology [ACC] criteria) when no coronary artery

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disease (CAD) imaging evaluation (e.g., myocardial perfusion imaging (MPI), cardiac positron emission tomography (PET), stress echocardiography (SE), coronary computed tomography angiography (CCTA), or coronary angiography) has been performed within the preceding sixty (60) days." Added a Policy Guidelines section to the policy.

03/07/2019 Medical Policy Committee review

03/20/2019 Medical Policy Implementation Committee approval. All revisions track AIM

Guidelines. Replaced the last three Patient Selection Criteria bullets with five new criteria bullets regarding suspected coronary artery disease. Defined "symptomatic" for patients with suspected coronary artery disease, but standard methods of Framingham or ACC criteria are used instead of using SCORE to refer to risk of CAD. Added Table 1: Pre-Test Probability of Coronary Artery Disease

by Age, Gender and Symptoms to Policy Guidelines.

12/10/2019 Coding update

03/05/2020 Medical Policy Committee review

05/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Replaced the second to last

solid criteria bullet with bulleted criteria from AIM Guidelines regarding preoperative cardiac evaluation of asymptomatic patients undergoing non-cardiac

surgery.

10/06/2020 Coding update

06/03/2021 Medical Policy Committee review

06/09/2021 Medical Policy Implementation Committee approval. Minor revisions made to a

table from AIM Guidelines for when a patient is considered symptomatic.

Coverage eligibility unchanged.

12/02/2021 Medical Policy Committee review

12/08/2021 Medical Policy Implementation Committee approval. Tracks AIM Guidelines

revisions related to pre-TAVR and pre-valve surgery.

06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

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Policy # 00153

Original Effective Date: 07/15/2005 Current Effective Date: 10/20/2024

01/05/2023 Medical Policy Committee review

01/11/2023 Medical Policy Implementation Committee approval. Extensive revisions to the

Coverage and Policy Guidelines sections.

06/01/2023 Medical Policy Committee review

06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

06/06/2024 Medical Policy Committee review

06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

Next Scheduled Review Date: 06/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)[‡], copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	75574
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: 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 eligibility for coverage.

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