



## FEP Medical Policy Manual

### FEP 6.01.43 Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

**Annual Effective Policy Date: January 1, 2024**

**Original Policy Date: September 2012**

**Related Policies:**

6.01.03 - Computed Tomography to Detect Coronary Artery Calcification

6.01.59 - Coronary Computed Tomography Angiography With Selective Noninvasive Fractional Flow Reserve

## Contrast-Enhanced Computed Tomographic Angiography for Coronary Artery Evaluation

### Description

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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 (ie, noninvasive stress testing and/or coronary angiography).

#### OBJECTIVE

The objective of this evidence review is to evaluate whether coronary computed tomography angiography (CCTA) improves health outcomes compared with alternative testing strategies and/or standard of care. Three major indications for cardiac or CCTA are considered: (1) evaluation of patients with acute chest pain without known coronary disease presenting in the emergency department setting, (2) evaluation of stable patients with signs and symptoms of coronary artery disease in the non-emergency department setting, and (3) evaluation of anomalous coronary arteries.

## POLICY STATEMENT

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

Contrast-enhanced CCTA for evaluation of individuals with stable chest pain and meeting guideline criteria for a noninvasive test in the outpatient setting (see Policy Guidelines) is considered **medically necessary**.

Contrast-enhanced CCTA for evaluation of individuals with suspected anomalous (native) coronary arteries is considered **medically necessary**.

Contrast-enhanced CCTA for coronary artery evaluation is considered **investigational** for all other indications.

## POLICY GUIDELINES

The 2012 collaborative medical association guidelines for the diagnosis and management of individuals with stable heart disease list several class I recommendations on the use of noninvasive testing in individuals with suspected stable ischemic heart disease. A class I recommendation indicates that a test should be performed. In general, individuals with at least intermediate risk (10% to 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.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

Coronary computed tomographic angiography 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

### 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 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).<sup>65</sup>

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 ( $\leq 1$  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."

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 1).<sup>37</sup>

**Table 1. 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	B
	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	B
	"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	C

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	B
	"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	C
	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	B
	"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	C
	"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	C
	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	C

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.<sup>66</sup> Coronary computed tomography angiography (CCTA) was considered appropriate for:

- 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 electrocardiography (ECG) has been done and indicates ST-T changes or Q waves.<sup>67</sup>

## Society of Cardiovascular Computed Tomography

The Society of Cardiovascular Computed Tomography (SCCT, 2021) published an expert consensus document on CCTA.<sup>68</sup> Recommendations on use of CCTA in select patients are included in Table 2. In addition to the recommendations listed below, the expert consensus included additional recommendations in several patient populations, including patients with known CAD.

**Table 2. 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 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.

## 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.

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
March 2014	Replace policy	Policy updated with literature review, references 18, 19, 43, 45-48, 57-59 added, others removed. No change to policy statement.
March 2015	Replace policy	Policy updated with literature review through October 16, 2014; references 21, 23-24, 27, and 64 added; reference 65 updated. No change to policy statements.
March 2016	Replace policy	Policy updated with literature review through October 20, 2015; references 19 and 22-28 added. Medically necessary indication added for stable chest pain.
March 2017	Replace policy	Policy updated with literature review; references 12, and 18-19 added. Requirement for invasive angiography prior to computed tomography angiography removed from the policy statement on anomalous coronary arteries. Policy title changed to "Contrast-Enhanced Coronary Computed Tomography Angiography for Coronary Artery Evaluation,."
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; references 29 and 31 added; reference 60 updated. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through July 10, 2018; references 12, 14, 21-23, and 28-29 added. Policy statements unchanged.
December 2019	Replace policy	Policy updated with literature review through June 26, 2019; references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 20, 2020; references added. Edits made to Policy section; statements otherwise unchanged.
December 2021	Replace policy	Policy updated with literature review through July 15, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through August 1, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through July 24, 2023; references added. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.