

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Cardiac CT, Coronary CT Angiography, Calcium Scoring and CT Fractional Flow Reserve

- Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/Coronary Plaque Analysis (AI-CPA)
- Cardiovascular Computed Tomography (CVCT)
- Cardiovascular Multislice CT (MSCT)
- Multidetector Row Spiral Computed Tomography (MDCT Scan)
- Multislice Detector Computed Tomography
- Multislice Tomography

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	 (CPT codes 75572, 75573, 75574) Noridian has retired LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease L38615) (CPT 75580) Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/Coronary Plague Analysis (L39883) (CPT 0623T-0626T)
Local Coverage Article (LCA)	LCA Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease A58097 Billing and Coding: Coronary Computed Tomography Angiography (CCTA) (A57552) Addresses CPT Code 77571

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Billing and Codi	ling: Artificial Intelligence Enabled CT Based
Quantitative Co	pronary Topography (AI-QCT)/Coronary Plaque
Analysis (AI-CF	PA) (A59771) (CPT 0623T-0626T)

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For Non-Medicare Member

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Source	Policy
Artificial Intelligence Enabled CT Based	There is insufficient evidence in the published medical literature
Quantitative Coronary Topography (Al-	to show that this service/therapy is as safe as standard
OCT //Coronary Plaque Analysis (Al-	services/therapies and/or provides better long-term outcomes
CPA) (CPT 0623T-0626T)	than current standard services/therapies
Cardiac CT Angiography (CTA)	Kaiser Permanente has elected to use the MCC* Care Guideline:
(CPT 75574)	Cardiaa CT Angiagraphy (CTA) (A 0492) for modical pagasaity
	determinational For appage to the MCC Clinical Cuidelines
	criteria, places and the MCC Cuideline Index through the
	criteria, piease see the MCG Guideline index through the
	provider portal under Quick Access.
Coronary Artery Calcium Score with	Repeat CAC measurement not indicated within less than 5
Computed Tomography (CT)	years.
Multidetector Computed Tomography	
(MDCT)	Adapted from KPWA ASCVD Primary Prevention Guideline (Oct
	2020)
	Coronary artery calcium scoring may be indicated for
	asymptomatic patients with 1 or more of the following :
	 Intermediate ASCVD risk* indicated by ALL of the following
	 Age 40-75 without DM and with LDL-C levels ≥ 70
	mg/dL
	 At a 10-year ASCVD risk* of ≥ 7.5% and < 20 %
	 Risk status or decision about statin therapy is uncertain
	For these patients, treatment with statin therapy may be withheld
	or delayed if CAC = 0, except in cigarette smokers and those
	with a strong family history of premature ASCVD. A CAC score of
	1–99 favors statin therapy, especially in those aged \geq 55 years.
	For any patient, if the CAC score is ≥ 100 or ≥ 75 th percentile,
	statin therapy is indicated.
	• May be considered in select adults age 40-75 with ALL of the
	following
	 Borderline elevated ASCVD risk (5-7.4% 10-vear
	ASCVD risk*)
	• The presence of CAC may change decision-making
	with regard to statin treatment and intensity of ASCVD
	risk factor modification
	Routine CAC measurement is not recommended for:
	 Patients at low (< 5% 10-year risk) or high (≥ 20% 10-year
	risk) ASCVD risk
	Patients who are unlikely to initiate treatment even if CAC is
	identified
	*ASCVD Risk Estimator Plus (American College of Cardiology)
	(+ + + + + + + + + + + + + + + + +
Fractional Flow Reserve CT	FFR-CT is considered medically necessary when ALL of the
CPT 75580	following criteria are met:
	Patient has symptoms consistent with myocardial ischemia
	CCTA has been performed in the preceding 90 days
	There is at least one 40%-90% coronary stenosis located in the proximal
	or middle segment of a major native coronary artery or a named branch
	thereof which is of uncertain functional significance.

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If requesting this service, please send the following documentation to support medical necessity:

Last 6 months of clinical notes from requesting provider &/or specialist (cardiology)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality worldwide. Currently invasive coronary angiography is the gold standard for coronary artery lumen assessment. It provides high spatial resolution and accurately determines the location, extent, and severity of coronary obstructive lesions. It also allows immediate intervention if needed. Coronary angiography, however, is an invasive procedure, has a small risk of serious complications, and requires a period of observation for several hours in a monitoring unit. Moreover, it was reported that nearly 40% of these procedures result in normal findings. This has led to a growing interest in the development less invasive methods for evaluating coronary anatomy, especially in stable patients at low to moderate risk of disease (Vembar 2006, Miller 2008).

Numerous anatomic and functional noninvasive tests for detecting CAD have emerged and are rapidly developing. Among these are stress echocardiography, nuclear perfusion studies, SPECT, magnetic resonance angiography, and others. More recently, computed tomography has been used for the evaluation of CAD. Electron beam computed tomography (EBCT) was initially used to assess coronary artery calcium as a marker of atherosclerosis. The first generation of multislice computed tomography (MSCT), also known as multidetector computed tomography (MDCT) scanners were introduced in the 1990s. The 4-slice scanner was developed to provide noninvasive direct visualization of the coronary arteries and led to significant improvements in spatial resolution compared to EBCT. However, it had motion artifacts, low resolution, long acquisition time, and up to 22% of the segments were non-assessable. The 4-slice CT thus rapidly evolved to16, 32, 40, and 64-slice CT scanners. The 16-slice scanner has better spatial resolution, faster gantry rotation, and larger coverage resulting in significantly shorter breath hold and less motion artifacts than those with 4-slice. The 64-slice scan generation, introduced in 2004, further improved the resolution, decreased the slice thickness, and reduced the acquisition time to less than 10 seconds. The entire procedure can be performed in approximately ten minutes. Systems with 256 and 320 slices and others with 64 slices but with 2 x- ray tubes (dual –source CT or DSCT) have recently been introduced (Gertz 2006, Vembar 2006, Berman 2006, Min 2009).

With the newer scanners, electrocardiographically synchronized images can be taken through the entire heart in the time of one breath hold. Synchronizing the location of the peak of QRS complex in the ECG with the projection data allows the reconstruction and visualization of anatomy at various phases of the cardiac cycle thus making functional imaging possible (Cademartiri 2005, Vembar 2006, Budoff 2008).

MDCT technology, however, has its limitations; it does not have the ability to correctly identify and differentiate between functionally significant and nonsignificant stenosis, or allow for intervention during the examination if needed. Positive findings frequently require confirmation with selective cardiac catheterization angiography, or stress myocardial perfusion to evaluate the functional significance. One of the difficulties in imaging the coronary vessels is the constant motion of the heart, which leads to artifacts and influences the image quality even with the significant improvements in the technology. Reducing the heart rate to 50-60 bpm with beta-blockers, now routinely used by most investigators, increases the cardiac rest period and reduces, but does not eliminate motion artifacts. To date, it is not possible to perform CT angiography in patients with atrial fibrillation unless it is highly regular.

One other significant problem, even with the most recent generations, is the inability of the MDCT to assess the degree of luminal obstruction within a calcified zone when there is dense calcification of the coronary arteries. This may lead to relatively high rate of false positive results and overestimate the severity of the disease. The use of MDCT is also limited for in-stent visualization, for evaluation of distal anastomosis among patients with

previous bypass graft surgery, and for patients with higher body mass index. Moreover, MDCT requires the administration of contrast material and exposure to ionizing radiation. The radiation dose used is equivalent to 2-3 times the dose typically used during an invasive angiogram. This may be considered a low radiation exposure but might be of concern among women in childbearing age, or younger individuals who may use the test repeatedly. History of severe allergic reactions to an iodinated contrast material or of impaired renal function (creatinine level >1.5 mg/dL) are contraindications to CT coronary angiography (Garcia 2005, De Roos 2006, Leber 2006, Berman 2006, Hoffmann 2006, Rixe 2009, Min 2009).

Medical Technology Assessment Committee (MTAC)

Ultrafast CT in the Screening and Diagnosis of CAD

02/11/2002: MTAC REVIEW

Evidence Conclusion: In conclusion, the results of these studies indicate that in a population where CAD is more prevalent, the absence of coronary calcification is more helpful in ruling out CAD than is the detection of calcium in confirming the presence of CAD. Ultrafast CT seems promising, but as yet, there is no evidence that it may substitute angiography, but can be helpful in excluding or increasing the likelihood of significant CAD in certain situations.

Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. AJR 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

12/08/2004: MTAC REVIEW

Ultrafast CT in the Screening and Diagnosis of CAD

Evidence Conclusion: A screening test for preclinical coronary artery disease among asymptomatic individuals, and A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: There is insufficient published evidence to determine the value of EBCT (Ultrafast CT) as a screening test for coronary artery disease among asymptomatic individuals. Ideally, a screening test should be highly sensitive in detecting previously undiagnosed disease and should lead to changes in management that improves outcomes. The meta-analysis and observational studies reviewed evaluated EBCT coronary artery calcium as a risk predictor of future coronary events among asymptomatic individuals. These studies suggest that coronary artery calcium detected by EBCT may be an independent predictor for coronary events and may add to the information provided by the Framingham risk score. However, the studies had some threats to validity that may limit generalization of the results. The majority is office-based and included self-referred individuals or others at high risk referred by their primary care physicians for further evaluation. Risk factors were self-reported and not measured in more than one study. Different techniques and scans were used, and there was no established cut-off level for calcium scores. The endpoints included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. The endpoint in one of the studies was all-cause mortality that might be due to other causes than coronary atherosclerotic diseases. None of these observational studies examined the influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. There is no evidence that more effective therapy or management could be provided by evaluating CAC score beyond that provided based on FRS. A recent RCT showed that the detection of coronary artery calcium among asymptomatic individuals was not associated with behavior modification or reduction of their cardiac risk scores. This RCT also had its limitations. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: The studies reviewed show that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies reviewed in the meta-analysis, and the more recent study.

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The sensitivity was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results.

Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary artery calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. AJR 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Virtual Coronary Angioscopy 04/03/2006: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to support the use of MSCT as a method of screening for CAD among healthy, low risk populations, or asymptomatic patients with known risk factors. There is insufficient evidence that the technology is as beneficial as catheter angiography in the diagnosis of CAD. There is insufficient evidence to support the use of MSCT scanning in monitoring progress of the disease and its outcome after an intervention, in patients with confirmed disease. There is insufficient evidence that the technology improves health outcomes. A multicenter study (CorE 64), and study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway.

Articles: The search yielded around 170 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. The search revealed several studies using 4, 8, and 16-slice CT scanners for the detection of coronary artery lesions. A recent meta-analysis of 24 of these studies was also identified, as well as seven studies that used the 64-slice CT angiography for detecting CAD stenosis and comparing the technology with invasive coronary angiography. The meta-analysis and four of the studies on the 64-slice scanners were critically appraised. Fine JJ, Hopkins CB, Ruff N, et al. Comparison of accuracy of 64-slice cardiovascular computed tomography with coronary angiography in patients with suspected coronary artery disease. Am J Cardiol. 2006; 97:173-174. See Evidence Table. Leber Aw, Knez A, von Ziegler F, et al. Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography. A comparative study with guantitative coronary angiography and intravascular ultrasound. J Am Coll Cardiol. 2005; 46:147-154. See Evidence Table. Raff G L, Gallagher MJ, O'Neill WW, et al. Diagnostic accuracy of noninvasive coronary angiography using 64-slice spiral computed tomography. J Am Coll Cardiol. 2005; 46:552-557. See Evidence Table. Ropers D, Rixe J, Anders K, et al. Usefulness of multidetector row spiral computed tomography with 6.4x0.6 mm collimator and 330 -ms rotation for the noninvasive detection of significant coronary artery stenoses. Am J Cardiol. 2006; 97:343-348. See Evidence Table. Schuijf JD, Bax JJ, Shaw LJ, et al. Meta-analysis of comparative diagnostic performance of magnetic resonance imaging and multislice computed tomography for noninvasive coronary angiography. Am Heart J. 2006; 151:404-411. See Evidence Table.

The use virtual coronary angioscopy of in the evaluation of coronary artery disease does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

02/05/2007: MTAC REVIEW

MDCT in the Treatment of Coronary Heart Disease

Evidence Conclusion: The patient-based analysis of the results of the studies, as presented individually or pooled in meta-analyses show high sensitivity and negative predictive values, but lower specificity and positive predictive value of the MDCT angiograms in the diagnosis of CAD in selected patients. This indicates that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients, but at the expense of up to 25% false positive tests among population groups with a high prevalence of CAD. The latter

would overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be generalizable to a broader lower-risk population. There is insufficient evidence to determine whether using the technology to diagnose coronary artery stenosis improves the net health outcomes. The published literature on the use of MDCT angiography in an ER does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. There are no published data to date on the effect of the using the technology on patient treatment or management decisions. A multicenter study (CorE 64) and a study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway. Articles: The search yielded around 55 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Three meta-analyses published after the last review were identified, as well as several small studies on MDCT with patient sizes ranging from 51 to 129. Four studies (Nikolaou 2006l, Plass 2006, Schuijf 2006, and Muhlenbruch 2006) compared the technology with invasive coronary angiography, Dewey et al, compared the 16-slice scanner with exercise electrocardiography, in one study and MRI in another study using the invasive angiography as the gold standard. Four published studies evaluating the use of MDCT for patients presenting to the ER with acute chest pain were identified. None of the latter studies compared the technology to the gold standard of invasive angiography, and only two used the 64-slice CT scans. All meta-analyses and recent studies were reviewed. The meta-analysis that included the most recent studies that used the newest denerations of MSCT (> 16 slices), compared MDCT to invasive coronary angiography, and had a valid methodology was critically appraised. A recent study comparing the 64-slice MDCT with invasive angiography, and another evaluating its use in patients presenting to the emergency room with acute chest pain were also selected for critical appraisal. Hamon M, Biondi-Zoccai GG, Malagutti P, et al. Diagnostic performance multislice spiral computed tomography of coronary arteries as compared with conventional invasive coronary angiography. J Am Coll Cardiol. 2006; 48:1896-1910. See Evidence Table. Nikolaou K, Knez A, Rist C, et al. Accuracy of 64-MDCT in the diagnosis of ischemic heart disease, AJR 2006; 187;111-117, See Evidence Table, Gallagher MJ. Ross MA, Raff GL, et al. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. Ann Emerg Med. 2006; See Evidence Table.

The use of MDCT in the treatment of coronary heart disease does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

04/02/2007: MTAC REVIEW

Ultrafast CT in the Screening and Diagnosis of CAD

Evidence Conclusion: There is some evidence that CAC may add a prognostic incremental value to Framingham risk score among selected asymptomatic individuals. Indirect evidence suggests that asymptomatic individuals at intermediate risk might potentially benefit from adding CAC to the risk assessment. The majority of the participants in the studies reviewed were Caucasians which may limit generalization of the results. The studies do not provide an optimal coronary calcium threshold. There is no single cutoff value that defines a high score. The coronary calcification differs according to age, sex, and race. There is no evidence to date that CAC scoring would result in an intervention that would improve CHD related health outcomes among individuals at an increased risk for CHD. The test results may lead to unnecessary invasive procedures, or overtreatment in some patients.

<u>Articles</u>: The search yielded around 50 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. <u>Use of EBCT for coronary artery disease screening</u>:

The search identified a recent meta-analysis of observational studies (Greenland 2007) and several prospective cohort studies that evaluated EBCT coronary artery calcium (CAC) score as a risk marker predicting the likelihood of future coronary events among asymptomatic patients. It also revealed two articles on the St. Francis Heart Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first reported on the prospective cohort study, and the second on the RCT embedded in the cohort. The meta-analysis and the two articles on the St. Francis Heart Study were selected for critical appraisal. Use of EBCT for coronary artery disease diagnosis: The search did not reveal any newly published large valid study on the use of CAC scoring in the detection of coronary artery stenosis among symptomatic patients. The following articles were critically appraised: Greenland P, Raggi P, Harrington R, et al. ACC/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment an in evaluation of patients with chest pain. J Am Coll Cardiol. 2007; 49:378-402. See Evidence Table. Arad Y, Goodman KJ, Roth M, et al. Coronary calcification, coronary disease risk factors, C-reactive protein, and atherosclerotic cardiovascular disease events. The St. Francis Heart Study. J Am Coll Cardiol. 2005: 46:158-165. See Evidence Table. Arad Y, Spadaro LA, Roth M, et al. Treatment of asymptomatic adults with elevated coronary calcium scores with atorvastatin, vitamin C, and vitamin E. The St. Francis Heart Study randomized clinical trial. J Am Coll Cardiol.2005;46:166-172. See Evidence Table.

The use of EBCT in the treatment of coronary artery calcium scoring does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

06/01/2009: MTAC REVIEW

MDCT in the Treatment of Coronary Heart Disease

Evidence Conclusion: Use of 64-multidetector computed tomography (MDCT) for the diagnosis of coronary artery stenosis in nonemergent settings: The published studies that evaluated the use of MDCT scanners in the diagnosis of coronary artery stenosis had generally valid methodology but were relatively small and mainly conducted among selected patients with stable conditions who were referred for invasive coronary angiography for a known or suspected CAD. The technology was not assessed for screening healthy, asymptomatic, or lowrisk individuals. The meta-analyses that pooled the results of the published studies had some variations in their inclusion/exclusion criteria, but a large number of same studies were included in all. The participants in ACCURACY (Budoff 2008) and CORE-64 (Miller 2008) studies, not included in the meta-analyses, were also patients with suspected symptomatic CAD referred for conventional coronary angiography. ACCURACY excluded patients with a known history of CHD, but no exclusions were made based on coronary artery calcium scoring or BMI. On the other hand, CORE 64 included patients with or without a history of CAD and excluded those with coronary artery calcium score >600 or BMI >40. Only coronary artery segments >1.5 mm was included in the analysis. These two studies as well as the other included in the meta-analyses performed patient-based and vessel-based analyses. Per-segment analyses were also performed in several studies. Accuracy of 64-slice MDCT. The patient-based analysis of the results of the studies, as presented individually or pooled in metaanalyses show high sensitivity (85-99%) and negative predictive values (95-100%), but lower specificity (83-91%) and positive predictive value (64-91%) of the MDCT angiograms in the diagnosis of significant (>50%) stenosis of CAD in selected patients. The technology was less sensitive (75-85%) but more specific (90-96%) in detecting stenosis per vessel. The accuracy of the test varied widely by artery and was highest for the left main artery followed by the left circumflex artery. These results indicate that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients with a suspected disease. This however could be at the expense of more than 20% false positive tests among population groups with a high prevalence of CAD. Impact on management and health outcomes: There was insufficient evidence to determine the effect of 64-slice on patient management or net health outcomes. The published studies to date evaluated_MDCT angiography in respect to its accuracy in identifying coronary stenosis, but not its effect on the treatment decisions, patient management, and health outcomes. Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain. The published literature on the use of MDCT angiography in emergency departments (ED) does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. Hoffmann 2009 (ROMICAT study), as well as earlier smaller studies that evaluated the use of the technology in the ED, did not compare it to the gold standard of catheter angiography, but used a combination of noninvasive tests and observations as a surrogate gold standard. The ROMICAT study aim was to determine the usefulness of MDCT angiography in patients with acute chest pain who presented to an emergency department and were admitted with low to intermediate risk for acute coronary syndrome. However, the results of the CT angiography findings were not provided to the physicians managing the patients, and thus it is not possible to determine whether the management or outcomes would have been altered based on the CT angiography findings. It is uncertain whether the clinicians would have performed less stress tests, more invasive angiograms, treated the patients more or less aggressively, or discharged the patients earlier had they known the results of the CT angiograms.

Articles: The search yielded around 325 articles on CT angiography. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Six meta-analyses published after the last review were identified. Four evaluated the diagnostic performance of the 64-slice CT scanners, one compared the performance of the 16 vs. the 64-slice scanners and another evaluated all 4, 16-slice, and 64 slice CT scanners. Two of the four metaanalyses on 64-slice scanners were performed by the same group of investigators (Mowatt and colleagues) and included the same studies. The literature search also identified two more recent multicenter studies (ACCURACY, and CORE 64) on the accuracy of the 64-slice CT scans in non-emergent settings, and one study on patients presenting to an emergency department (ROMICAT study). None was included in the meta-analyses. There were no published studies that prospectively compared MDCT to other noninvasive stress testing. The most recent valid meta-analysis that compared the performance of 64-slice scanners to invasive coronary angiography was selected for critical appraisal, as well as the newer studies ACCURACY, CORE 64, and ROMICAT. The references for the studies reviewed are: Mowatt G, Cook JA, Hillis GS, et al. 64-slice computed tomography angiography in the diagnosis and assessment of coronary artery disease; systematic review and meta-analysis. Heart. 2008; 94:1386-1393. See Evidence Table. Budoff MJ, Dowe D, Jollis JG, et al. Diagnostic performance of 64-multdetector row coronary computed tomographic angiography for evaluation of coronary artery stenosis in individuals without known coronary artery disease. Results from the prospective multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary © 2006 Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top

Angiography) trial. J Am Coll Cardiol 2008; 52:1724-1732. See <u>Evidence Table</u>. Miller JM, Rochite CE, Dewey M, et al. Diagnostic performance of coronary angiography by 64-Row CT. N Engl J Med 2008;359:2324-2336. See <u>Evidence Table</u>. Hoffmann U, Bamberg F, Chae CU, et al. Coronary computed tomography angiography for early triage of patients with acute chest pain. The ROMICAT (Rule Out Myocardial Infarction using Computer Assisted Tomography) trial. J Am Coll Cardiol 2009; 53:1642-1650. See <u>Evidence Table</u>.

The use of MDCT in the treatment of coronary heart disease does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

CORONARY ARTERY CALCIUM (CAC) SCORING WITH COMPUTED TOMOGRAPHY, FOR CARDIOVASCULAR DISEASE RISK ASSESSMENT

Date: 10/12/2020

Evidence Conclusion:

- There is evidence from published long-term large longitudinal population studies indicating that:
 - CAC is strongly associated and in a graded fashion with 10-year risk of incident ASCVD in asymptomatic White, Black, Hispanic and Chinese American men and women 45-84 years of age with no known history of CHD.
 - CAC scoring provides additional predictive information on ASCVD events and mortality, beyond the traditional risk factors, in men and women at different age groups, races, ethnic background, at different levels of risk, and in the presence or absence of comorbid conditions such as diabetes mellitus.
- There is insufficient published evidence, to date, from valid RCTs with long-term follow-up to determine that treatment guided by CAC scoring levels in addition to the traditional risk factors have an impact on patient management and /or health outcomes in asymptomatic adults at intermediate CV risk.

<u>Articles:</u> The literature search identified multiple large long-term population-based observational studies conducted in the US and Europe published over the last 20 years, that examined the association between CAC scoring and incidental CVD events and mortality in asymptomatic individual with no known coronary artery disease and its potential utility for CVD risk stratification in asymptomatic population. the largest population cohorts and/or those with longest follow-up duration were included in the review. The search did not identify any recent RCT with important clinical outcomes to determine the impact of CAC on guiding statin therapy an improving outcome in individuals at intermediate ASCVD risk.

The use of Coronary Artery Calcium (CAC) Scoring with Computed Tomography, for Cardiovascular Disease Risk Assessment does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Fractional Flow Reserve Computed Tomography (FFRCT) for CAD

MTAT Review: September 2021 Evidence Conclusion:

The Medical Technology Assessment Team (MTAT) reviewed the evidence on Fractional Flow Reserve Computed Tomography (FFRCT) Software (HeartFlow, Inc.) for Coronary Artery Disease (CAD) on September 7, 2021.

- Overall, there is a large body of literature examining the clinical validity and clinical utility of FFRCT in patients with known or suspected coronary artery disease.
- We identified one systematic review/meta-analysis (Luo, 2021) and two health technology assessments (ECRI; Hayes, Inc.) that addressed the clinical question. •
- A Hayes, Inc. (2020)1 assessment, which was used as the primary evidence source for this review, included 3 systematic reviews/meta-analyses and 28 additional studies (20 on clinical validity of FFRCT, 8 on clinical utility of FFRCT). Regarding evidence quality, the report noted:
 - The body of evidence concerning FFRCT for detection of HSS in patients with known or suspected CAD is large in size and moderate in quality for clinical validity, but low in quality for clinical utility. Overall quality was determined based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of data to general practice.
 - It was further noted: The available studies of FFRCT have not provided sufficient evidence that this technique provides information that improves patient management, primarily due to a lack of randomized controlled trials (RCTs).
- Our bridge search identified 7 additional individual studies:
 - One small prospective comparative study2 (N=42) evaluated the clinical validity (i.e., diagnostic performance) of FFRCT in patients with suspected or known CAD. Consistent with the findings of the Hayes, Inc. review, diagnostic accuracy was better than CCTA alone for evaluation of CAD.

- Two comparative studies (one prospective cohort study2 and one RCT3) and 5 observational studies4-8 examined clinical utility (total N=4,372).
 - Overall, there were statistically significant correlations between reduced FFRCT values and 1 or more types of ACE.
 - There is recent data available from a large RCT3 showing that FFRCT led to 22% reduction in ICA use (p=0.01) and no difference in symptoms, quality of life, major adverse cardiac and cerebrovascular events, or use of coronary revascularization vs. no FFRCT in patients with stable chest pain (Curzen, 20213; N=1,400); however, the study had a follow-up period of only 9 months. There remains a need for longer term clinical utility data.
- The studies identified in our search were limited by small sample sizes, lack of randomized studies with adequate follow-up data, and retrospective, non-comparative designs.
- Thus, the results of the studies identified in our bridge search (for both clinical validity and clinical utility) are in line with the findings of the Hayes, Inc. review.

Overall Conclusion(s)

- The quality of the evidence on the clinical validity of FFRCT in patients with known or suspected CAD is moderate. The quality of the evidence on the clinical utility of FFRCT in patients with known or suspected CAD is low.
- Therefore, the overall quality of the body of evidence on FFRCT in patients with known or suspected CAD is low.
- Additional trials with randomized controlled designs or high-quality comparative studies with longterm follow-up periods are needed to determine whether use of FFRCT in patients with known or suspected CAD leads to clinically meaningful changes in treatment decision-making and health outcomes.

Hayes Technology Assessment

Noninvasive Computed Fractional Flow Reserve from Computed Tomography (FFRCT) for Diagnosis of Coronary Artery Diesase

Dec 11, 2020 ; annual review 1/30/2023

Technology Description

FFRCT is a noninvasive alternative to FFR testing that involves computer-assisted processing of CCTA images to estimate changes in blood pressure inside coronary arteries that have partial or intermediate stenosis. By using information from CCTA to model fluid dynamics of the coronary arteries, FFRCT seeks to determine whether the stenotic lesion causes an appreciable reduction in blood flow to the heart, which may lead to myocardial ischemia or infarction, and whether the lesion can be treated medically or requires a percutaneous coronary intervention (PCI), such as balloon angioplasty and stenting. FFRCT is an alternative to invasive assessment of FFR that uses a pressure-sensing wire inserted into the coronary arteries. A stenosis with an FFRCT value ≥ 0.80 creates a small drop in blood pressure, has a low probability of causing inducible ischemia, and is not considered to need PCI. FFRCT is performed using already obtained CCTA images at a center equipped with the specialized software.

Conclusion

The available studies have provided consistent evidence that FFRCT is more accurate than CCTA alone for detection of HSS but insufficient evidence to evaluate FFRCT relative to other noninvasive methods such as CCTP, SPECT, PET, and CMR. There is also insufficient evidence to evaluate the clinical utility of FFRCT relative to invasive FFR. The only available study with prospective controls found that FFRCT-guided management reduced the use of unnecessary ICA in a significant proportion of patients with no increased occurrence of adverse clinical outcomes. However, this study did not randomize patients to FFRCT versus invasive testing and it involved only 1 year of follow-up. Studies of FFRCT for prediction of CAD events found correlations between reduced FFRCT and adverse clinical outcomes but had significant shortcomings, such as limited or incomplete use of multivariate analysis to identify independent predictors. FFRCT does not pose any notable safety concerns. Although most studies in the evidence base included patients with stable chest pain and suspected or known CAD, most did not limit the patient population to those with intermediate coronary artery blockages and reported results for all lesions, making it difficult to determine which patients would benefit from testing. Additional studies, particularly of clinical utility, are needed to determine the long-term efficacy and safety of FFRCT for guidance of CAD management in this patient population.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Noninvasive Computed Fractional Flow Reserve from Computed Tomography (FFRCT) for Diagnosis of Coronary Artery Disease. Dallas, TX: Hayes; January 30, 2023. Retrieved February 21, 2023, from https://evidence.hayesinc.com/report/dir.noninvasiveffrct3647

Applicable Codes

Medicare & Non-Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®	Description
Codes	
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
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)
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional

Coronary Artery Calcium Score

Medicare & Non-Medicare:

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®	Description
Codes	
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

Artificial Intelligence Enabled CT Based Quantitative Coronary Topography

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Non-Medicare: Considered Not Medically Necessary - experimental, investigational, or unproven

CPT®	Description
Codes	
0623T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data
	preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report
0624T	Automated quantification and characterization of coronary atherosclerotic plaque to assess
	severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography
0626T	Automated quantification and characterization of coronary atherosclerotic plaque to assess
	severity of coronary disease, using data from coronary computed tomographic angiography;
	review of computerized analysis output to reconcile discordant data, interpretation and report

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
04/27/2006	04/03/2006, 02/05/07, 07/13/2009 ^{MDCRPC} , 06/01/2010 ^{MDCRPC} , 04/05/2011 ^{MDCRPC} , 02/07/2012 ^{MDCRPC} , 12/04/2012 ^{MDCRPC} , 06/04/2013 ^{MDCRPC} , 10/01/2013 ^{MPC} , 4/1/2014 ^{MPC} , 01/06/2015 ^{MPC} , 12/01/2015 ^{MPC} , 10/04/2016 ^{MPC} , 08/01/2017 ^{MPC} , 06/05/2018 ^{MPC} , 06/04/2019 ^{MPC} , 06/02/2020 ^{MPC} , 06/01/2021 ^{MPC} , 06/07/2022 ^{MPC} , 06/06/2023 ^{MPC} , 05/07/2024 ^{MPC}	03/26/2025

MDCRPC Medical Director Clinical Review and Policy Committee MPC Medical Policy Committee

Revision	Description
History	
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
07/28/2016	Added retired LCD language
07/25/2017	Chest CT angiography no longer requires review
06/02/2020	Removed CPT code 71275 and reference for Chest CT Angiography since it does not require
	medical necessity review
03/06/2023	Addition of Medicare LCD, LCA links for Non-Invasive Fractional Flow Reserve (FFR) for stable
	Ischemic Heart Disease and applicable codes for Medicare added 0501-0504T.
08/08/2023	MPC approved clinical indications for Fractional Flow Reserve (FFR). Requires 60-day notice,
	effective date 01/01/2024.
01/31/2024	Updated CPT codes added new code 75580 effective 1/1/2024 and removed CPT 0501T, 0502T,
	0503T, 0504T which were deleted 1/1/2024 and replaced with 75580.
03/26/2025	Merged CT angiography and Cardiac CT angiography policies. Added new Medicare LCD L39883
	and Billing and Coding Article A59771 for artificial Intelligence Enabled CT Based Quantitative
	Coronary Topography (CPT Codes 0623T-0626T).