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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Coronary CT Angiography

- Cardiac CT Angiography
- Cardiovascular Computed Tomography (CVCT)
- Cardiovascular Multislice CT (MSCT)
- Contrast Enhanced Computed Tomographic Angiography
- Fractional Flow Reserve CT
- Multidetector Row Spiral Computed Tomography (MDCT Scan)
- Multislice Detector Computed Tomography
- Multislice Tomography

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 0501T, 0502T, 0503T, 0504T)**
Local Coverage Article (LCA)	LCA Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease A58097

For Non-Medicare Members

Cardiac CT Angiography (CTA) CPT 75574	Kaiser Permanente has elected to use the MCG* Care Guideline: Cardiac CT Angiography (CTA) (A-0483) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Fractional Flow Reserve CT CPT 0501T, 0502T, 0503T, 0504T	**Effective until January 1, 2024**

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	Send all cases to MD for review. **Effective January 1, 2024** FFR-CT is considered medically necessary when **ALL** of the 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.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

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)

For screening see:
Coronary Artery Calcium Score with Computed Tomography (CT) - CPT 75571

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).

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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)

Virtual Coronary Angioscopy

04/03/2006: MTAC REVIEW

Evidence Conclusion: All published studies on MSCT scanners investigated the accuracy of MCST in patients with known or suspected CAD, who was referred for evaluation with catheter angiography. None of the studies evaluated the technology for screening healthy, asymptomatic, or low risk individuals. Schuijf and colleagues' meta-analysis (2006) included 24 studies with 1,300 participants that compared MSCT scans head to head with invasive catheter angiography in patients with known or suspected CAD. The studies used one of the 4, 8, or 16 slice CT scanners. Those evaluating the 64-slice CT scans were not published to the date of analysis. The results of the meta-analysis show that the 4,8, and 16 MSCT scan generations had an overall high specificity (95%) and negative predictive value (97%) but lower sensitivity (85%) and positive predictive value (76%) compared to invasive angiography as the gold standard. Published studies evaluating 64-slice CT scanners had some differences in the methodology and patient characteristics, but all used invasive catheter angiography as the gold standard, included only patients with known or suspected CAD, excluded those with cardiac arrhythmias and unstable conditions, defined significant coronary stenosis as >50% lumen narrowing, and the majority used beta-blockers to reduce the heart rate. The trials ranged in size from 35 to 84 patients, used the same Sensation 64 CT Siemens Medical Solutions scanners, and almost all reported analysis of sensitivity, specificity, positive and negative predictive values. Analysis of MSCT performance was limited to coronary segments > 1.5 or 2 mm in diameter, and most studies used individual coronary vessels or vessel segments as the unit of analysis. Not all studies reported on the performance characteristics of MSCT using the patient as a unit of analysis. The results of the studies critically appraised show that 4-13% of the coronary segments were non-evaluable due to motion artifacts, severe calcified plaques, and/or other technical imaging problems. The sensitivity and specificity of MSCT for detecting >50% diameter reduction in the evaluated coronary segments ranged from 73% to 95% and from 80% to 97% respectively. Only two studies reported on the performance characteristics of MSCT using the patient as a unit of analysis showing a sensitivity of 95-96% and specificity of 90-91%. The negative predictive values ranged from 92-100% when segments were used as the unit of analysis and 93% to 98% when analyses were per patients. The positive predictive value on the other hand was much lower (as low as 56 % per segment and 83% per patient). Leber et al (2005) went a step beyond assessment of stenosis and evaluated the 64-MSCT scan for detecting and quantifying coronary atherosclerotic plaque compared to intravascular ultrasound (IVUS), and reported a 84% sensitivity and 91% specificity. This, however, was studied on a very small subgroup of only 18 patients with stable angina. The overall results of the published studies may indicate that MSCT scanning may have a high sensitivity of diagnosing CAD, and a high NPV that would accurately rule out CAD among the selected symptomatic patients with a negative MSCT scan result. However, all studies were small, conducted in single, highly specialized centers, conducted among selected intermediate to high risk patients, with stable conditions, regular heart rhythm, and a high prevalence of CAD. These factors in addition to analyzing the diagnostic performance of the technology based on the evaluable segments of the vessels only, would

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overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be generalizable to a broader population. In 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 quantitative 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: *Use of MDCT for the diagnosis of coronary artery stenosis* - The published studies evaluating the use of MDCT scanners in the diagnosis of coronary artery stenosis are all relatively small trials mainly conducted in single specialized centers, and 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 low risk individuals. The studies evaluated MDCT angiography in respect to its accuracy in identifying coronary stenosis (per segment, per-vessel and per- patient), but not its effect on the treatment decisions, patient management, and health outcomes. Certain segments or whole patients were excluded from the analysis due to nonassessable images, which would overestimate the accuracy of the test. Three recently published meta-analyses (Hamon 2006, Sun 2006, and Stein 2006) pooled the results of published individual small studies. There were some variations between the three meta-analyses in the inclusion/exclusion criteria, but many of the same studies were included in all three analyses. Hamon and colleagues' analysis included more up-to date studies, and only those using 16 or more slice MDCT scans. The other two meta-analyses included older studies with 4, 8, 12 as well as the newer 16 and 64-slice scans. The authors of all three meta-analyses performed per-segment, per-vessel, and per-patient analyses. The per-patient analysis would be the most relevant if the MDCT is intended for use as a substitute for invasive angiography. Overall, the results of the three meta-analyses show that MDCT angiography had a sensitivity ranging from 81-94%, and specificity ranging from 93-94% for the per-segment analysis. Analyses based on patients showed a sensitivity of 91 –95%, and specificity of 74-84%. The per-patient pooled positive likelihood ratios were 5.4 and 6 and negative likelihood ratios were 0.05 and 0.07 in the two analyses that reported them. Hamon and colleagues also pooled the results of the positive and negative predictive values which were 83% and 94% respectively for the per-patient analysis. Nikolaou and colleagues, 2006 evaluated the clinical value of the 64-slice computed tomographic (MDCT) in the diagnosis of coronary artery disease among 72 patients with and without a history of a known coronary artery disease (CAD) in a cardiology center in Germany. 40% of the participants had already been diagnosed with CAD and angiographically verified. Invasive coronary angiography was the gold standard and was evaluated by an independent observer blinded to the MDCT results. Scan results were analyzed by two independent experienced observers blinded to the invasive angiography results, and patients' history. 6% of patient-based and 10% of the segment-based CT angiograms were nonassessable. 64% of the assessable CT angiograms had a high image quality, 30% had moderate quality and 6% were poor. The results of this study showed a sensitivity of 86% and specificity of 94% for the per-segment analysis. These were 97% and 79% respectively for the per-patient
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analysis. The negative predictive value was 100% for patients with known CAD, and 93% for those with a suspicious disease. These rates were computed from very small number of patients with a high prevalence of CAD and would not necessarily apply to populations at a lower risk. *Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain:* The few studies that evaluated the use of the technology in the emergency room 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. Gallagher and colleagues, 2006 evaluated the diagnostic accuracy of the 64-slice multidetector computed tomographic (MDCT) coronary angiography compared to stress nuclear imaging for the detection of an acute coronary syndrome (ACS) or 30-day major cardiac adverse events. The study included 92 low-risk chest pain patients seen in the emergency department of a teaching hospital in Michigan USA. The participants had negative serial ECG and cardiac marker results at presentation to the ER. They were admitted to the emergency department observation unit for the chest pain diagnostic protocol (cardiac monitoring, serial ECG. and cardiac marker tests) 4 hours after arrival. Those with abnormal markers had repeat tests and ECG at 8 hours. If these latter tests were negative the patients received a stress nuclear imaging test followed by MDCT coronary angiography using 64-slice multidetector CT scanners. Patients were treated based on the findings of both tests, and then followed up for evidence of ACS or major adverse events within 30 days of their initial visit. Those with positive tests suggesting unstable angina underwent cardiac catheterization to confirm the diagnosis. The authors used clinical markers and outcomes as a surrogate gold standard, and 7 (7.6%) of the study participants were not included in the analysis due to uninterpretable MDCT images. The numbers were too small and show a MDCT sensitivity of 86% specificity of 92%, NPV of 99% and a PPV of 50%. Hoffmann et al, 2006 also assessed MDCT angiography among 103 patients presenting to the ER with acute chest pain in a university hospital in Massachusetts. The participants had no ischemic ECG changes and negative initial biomarkers. They all underwent contrast enhanced 64-slice MDCT coronary angiography before admission. The results were not compared to the gold standard of catheter angiography. The diagnosis of acute coronary syndrome was made by an expert panel blinded to the results of MDCT, based on the results of serial ECGs, cardiac biomarkers, and subsequent cardiac testing including exercise testing, stress perfusion imaging, or cardiac cauterization during the index hospitalization and 5-months follow-up. The results of the study showed that MDCT had a sensitivity of 100%, specificity of 82%, negative predictive value of 100%, and a positive predictive value of 47% in detecting a significant stenosis. These, however, were not verified with catheter angiography for all patients. Two other studies (White et al 2005, and Sato et al 2005) also evaluated MDCT use in small numbers of patients (N=69 and 31 respectively) admitted to ER with chest pain. They used the older 4 and 16 row CT detectors. Patients included also had non-diagnostic ECGs and normal cardiac enzymes. Invasive angiography was not used as a gold standard. The reference standards used were similar to those discussed earlier. The sensitivities and specificities were 83% and 96% respectively in White's study, and 95.5% and 88.9% respectively in Sato's study. This relatively moderate accuracy indicates that some cases might be missed, and others may undergo unnecessary invasive angiograms based on the results of the MDCT.
In 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 generations 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
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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.*

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 low-risk 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 meta-analyses 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 meta-analyses 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

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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 Angiography) trial. J Am Coll Cardiol 2008; 52:1724-1732. See Evidence Table. 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 Evidence Table. 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 Evidence Table**.**

The use of MDCT in the treatment of coronary heart disease 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.

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

CPT® Codes	Description
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report

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0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report
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)

Effective until January 1, 2024

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

CPT® Codes	Description
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)

Effective January 1, 2024

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

CPT® Codes	Description
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)
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model

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0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model 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**.

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]	08/08/2023

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

Revision History	Description
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.

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