

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Cardiac/Coronary Computed Tomographic Angiography (Cardiac/Coronary CTA): Contrast-Enhanced
Policy Number	6.01.34
Category	Technology Assessment
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. • If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, cardiac computed tomographic angiography (CTA), using at least a 64-slice computed tomography (CT) scanner, is considered **medically appropriate** for any of the following:
 - A. Cardiac CT for structure and morphology:
 1. Evaluation of cardiac or pericardial mass or tumor, cardiac thrombus, complications of cardiac surgery and/or pericarditis or constrictive pericarditis when an echocardiogram was performed and is inconclusive.
 2. Pre-procedural preparation and structural assessment of patients being considered for transcatheter aortic valve implantation (TAVI) or transcatheter aortic valve replacement (TAVR) to measure the aortic annulus and assess the coronary arteries in lieu of heart catheterization.
 3. Coronary vein mapping for lead placement in individuals needing left ventricular pacing.
 4. Pulmonary vein evaluation, when radiofrequency ablation for atrial fibrillation is planned.
 5. In place of magnetic resonance imaging (MRI) when there is clinical suspicion of suspected arrhythmogenic right ventricular dysplasia (ARVD) or arrhythmogenic cardiomyopathy (ARVC) with presyncope or syncope, when clinical suspicion is supported by established criteria for ARVD.
 6. Recurrent laryngeal nerve palsy due to cardiac chamber enlargement.
 7. In place of transesophageal echocardiogram (TEE) for assessment of left atrial appendage (LAA) occlusion device or to assess for thrombus.
 - B. Cardiac CT for congenital heart disease:
 1. Coronary artery anomaly evaluation, when a cardiac catheterization was performed, and not all coronary arteries were identified.

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2. Thoracic arteriovenous anomaly evaluation, when a cardiac MRI or chest CT angiogram was performed and suggested congenital heart disease.
3. Complex congenital heart disease evaluation, when no cardiac CT or cardiac MRI has been performed (e.g., because there is a contraindication to MRI), or cardiac CT or cardiac MRI was performed one or more years ago.

C. Cardiac CTA:

1. Evaluation of known coronary artery disease (CAD), documented by prior imaging stress test, cardiac catheterization, cardiac CT angiogram, coronary revascularization, carotid stenosis or stroke, peripheral artery disease, or aortic aneurysm, when the cardiac CTA is performed:
 - a. To evaluate post-graft patency after coronary artery bypass grafting (CABG) or re-do CABG.
 - b. To evaluate left main stent one time at six to twelve months.
 - c. To evaluate the location of the left internal mammary artery (LIMA) and/or right internal mammary artery (RIMA) prior to repeat bypass surgery.
2. For new, recurrent or worsening symptoms concerning for cardiac ischemia in individuals who have:
 - a. An intermediate or intermediate-high pretest probability of CAD (refer to Policy Guideline III); or
 - b. Persistent symptoms in individuals with low, intermediate or intermediate-high pretest probability of coronary artery disease after a normal stress test; or
 - c. Equivocal, borderline, abnormal or discordant prior noninvasive evaluation where obstructive CAD disease remains a concern (less than 90 days); or
 - d. Abnormal rest ECG findings, such as a new left bundle branch block (LBBB), or T-wave inversions, when ischemia is a concern; or
 - e. A prior coronary artery bypass graft (CABG) when only a graft patency is a concern.
3. Conventional coronary angiography has been unsuccessful, and patient is symptomatic.
4. Evaluation of coronary artery anomalies and other complex congenital heart disease of cardiac chambers or great vessels.
5. Diagnosis or treatment planning, where anomalous coronary artery(ies) are suspected, and patient is less than age 40 with history that includes one or more of the following:
 - a. Persistent chest pain brought on by exertion or emotional stress and normal stress test; or
 - b. Full sibling(s) with history of sudden death syndrome before age 40 or with documented anomalous coronary artery; or
 - c. Resuscitated sudden death and contraindications for conventional coronary angiography; or
 - d. Prior nondiagnostic coronary angiography in determining the course of anomalous coronary artery in relation to the great vessels, origin of a coronary artery, or bypass graft location; or
 - e. Syncopal episodes during strenuous activities.
7. Evaluation of newly diagnosed congestive heart failure or cardiomyopathy without known coronary artery disease:
 - a. To assess coronary arteries, when patient is low- or intermediate-risk on the pre-test probability assessment, the ejection fraction is less than 50%, and there is no exclusion to cardiac CTA; and
 - b. No cardiac catheterization, single-photon emission CT (SPECT), cardiac positron emission tomography (PET), or stress echocardiogram has been performed since the diagnosis of congestive heart failure or cardiomyopathy.
8. Equivocal coronary artery anatomy despite conventional cardiac catheterization.
9. Initial imaging study for individuals with hypertrophic cardiomyopathy and stable anginal symptoms.
10. When cardiac CTA will replace conventional invasive coronary angiography for the following indications:
 - a. Ventricular Tachycardia (six beat run or greater); or
 - b. Delayed presentation or retrospective evaluation of suspected Takotsubo syndrome (stress cardiomyopathy); or
 - c. Preoperative assessment of the coronary arteries in patient who is going to undergo surgery for aortic dissection, aortic aneurysm, or valvular surgery.

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11. To assess coronary involvement in individuals with systemic vasculitis (e.g. Giant Cell Arteritis, Takayasu's, Kawasaki's disease) when there are clinical features suggestive of underlying vasculitis.
- D. Cardiac Trauma: To detect aortic and coronary injury and potentially aid in the evaluation of myocardial and pericardial injury.
- II. Based upon our criteria and assessment of the peer-reviewed literature, cardiac CTA is considered **investigational** for all other indications.
- III. Based upon our criteria and assessment of the peer-reviewed literature, calcium scoring performed as part of a CTA procedure is considered **medically appropriate** for patients who are candidates for CTA, as pre-test knowledge of extensive calcification of the coronary segment in question may diminish the interpretive value of a cardiac CTA.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of noninvasive fractional flow reserve (FFR) following a positive coronary CTA is considered **medically appropriate** to guide medical decisions regarding the use of invasive coronary angiography (ICA) in patients with stable chest pain who are at intermediate risk of coronary artery disease (i.e., suspected or presumed stable ischemic heart disease).
- V. Based upon our criteria and assessment of the peer-reviewed literature, the use of automated quantification and characterization of coronary atherosclerotic plaque via CTA is considered **investigational**.

Refer to Corporate Medical Policy #6.01.13 Coronary Calcium Scoring.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

Refer to Corporate Medical Policy #11.01.10 Clinical Trials.

POLICY GUIDELINES

- I. The following are examples of contraindications for the use of cardiac CTA:
- A. Irregular heart rhythms (e.g., atrial fibrillation/flutter, frequent irregular premature ventricular contractions or premature atrial contractions, and high-grade heart block);
 - B. Multifocal atrial tachycardia;
 - C. Inability to lie flat;
 - D. Body mass index of greater than 40;
 - E. Inability to obtain a heart rate of less than 65 beats per minute after beta blockers;
 - F. Calcium score of greater than 1000;
 - G. Inability to hold breath for greater than eight seconds;
 - H. Renal insufficiency (creatinine greater than 1.8 mg/dl);
 - I. Evaluation of coronary stent patency, if the vessel is less than 3.0 mm in diameter (metal artifact limits accuracy);
 - J. Routine use in the evaluation of coronary arteries following heart transplantation in asymptomatic patient;
 - K. Evaluation of left ventricular function following myocardial infarction or when patient is in chronic heart failure;
 - L. Evaluation of patients with post-operative native or prosthetic cardiac valves who have technically limited echocardiograms, MRI or transesophageal echocardiogram (TEE);
 - M. First test in evaluating symptomatic patient (e.g., chest pain);
 - N. High pre-test probability for coronary artery disease;
 - O. Identification of plaque composition and morphology;
 - P. Myocardial perfusion and viability studies;
 - Q. Pre-operative assessment for non-cardiac, non-vascular surgery;
 - R. Repeat or routine follow-up of asymptomatic patient or patient with stable symptoms of coronary artery disease post-cardiac CTA.
- II. Per appropriateness criteria from a multidisciplinary cardiac CTA and cardiac MRI work group (Hendel et al., 2006), chest pain syndrome is defined as any constellation of symptoms that the physician feels may represent a complaint

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consistent with obstructive CAD. Examples of such symptoms, which are not exclusive to chest pain syndrome, include:

- A. Chest pain;
- B. Chest tightness;
- C. Chest burning;
- D. Dyspnea;
- E. Shoulder pain; or
- F. Jaw pain.

III. Clinical pre-test probability of CAD is a statistical tool used in the initial assessment of stable chest pain syndromes to estimate the likelihood that the symptoms are caused by obstructive coronary artery disease using the individual’s description of the symptoms, their age, and sex assigned at birth. The pre-test probability for obstructive coronary artery disease as the cause of the symptoms is categorized as the following:

- High: Equal or greater than 85% pre-test probability
- Intermediate/High: Between 66-85% pre-test probability
- Intermediate: Between 15-65% pre-test probability
- Low: Less than 15% pre-test probability

Clinical pretest probability of CAD in individuals with stable chest pain symptoms				
Age (years)	Sex at birth	Type of Symptoms		
		Cardiac (Chest pain/pressure/tightness)	Possibly cardiac (Including dyspnea/fatigue)	Noncardiac / Non-ischemic
30-39	Male	Intermediate	Intermediate	Intermediate
	Female	Intermediate	Low	Low
40-49	Male	Intermediate/High	Intermediate	Intermediate
	Female	Intermediate	Low	Low
50-59	Male	Intermediate/High	Intermediate/High	Intermediate
	Female	Intermediate	Intermediate	Low
60-69	Male	Intermediate/High	Intermediate/High	Intermediate
	Female	Intermediate/High	Intermediate/High	Intermediate
70-79	Male	High	Intermediate/High	Intermediate
	Female	Intermediate/High	Intermediate/High	Intermediate
>80	Male	High	Intermediate/High	Intermediate
	Female	Intermediate/High	Intermediate/High	Intermediate

DESCRIPTION

Computed tomographic angiography, or CTA, is a non-invasive imaging test that requires the use of intravenously administered contrast material and high-resolution, high-speed CT machinery to obtain detailed volumetric images of blood vessels. CTA can be applied to image blood vessels throughout the body; however to apply CTA in the coronary arteries, several technical challenges must be overcome, to obtain high-quality diagnostic images. Very short image acquisition times are necessary, to avoid blurring artifacts from the rapid motion of the beating heart. In some cases, premedication with beta-blocking agents is used to slow the heart rate below 60-65 beats per minute, to facilitate adequate scanning, and electrocardiographic triggering or retrospective gating is used to obtain images during diastole when motion is reduced. Rapid scanning is also helpful, so that the volume of cardiac images can be obtained during breath-holding.

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Very thin sections (less than 1 mm) are important to provide adequate spatial resolution and high-quality three-dimensional reconstruction images.

Cardiac CTA has been proposed as a noninvasive alternative to invasive coronary angiography (ICA). Applications include, but are not limited to, evaluation of obstructive coronary artery disease (CAD), coronary artery bypass graft patency, coronary artery stent patency, coronary artery aneurysm, delineation of coronary artery anomaly, and functional cardiac assessment.

It is recognized that calcium scoring is an integral part of CTA, to determine the risk-benefit of dye infusion.

Fractional flow reserve (FFR) is the ratio between the maximum blood flow in a narrowed artery and the maximum blood flow in a normal artery. The HeartFlow FFRCT (HeartFlow, Inc., Redwood City, CA) is coronary physiologic simulation software that has been approved by the U.S. Food and Drug Administration (FDA) to provide a non-invasive method of estimating FFR using standard coronary CTA image data.

Automated quantification and characterization of coronary atherosclerotic plaque is a service in which coronary computed tomographic angiography (CTA) data are analyzed using computerized algorithms to assess the extent and severity of coronary artery disease. The use of automated quantification and characterization of coronary atherosclerotic plaque is considered investigational at this time.

RATIONALE

Contrast-enhanced cardiac CTA can be performed using either multidetector-row CT (MDCT) or electron beam CT (EBCT). Multiple manufacturers have received Section 510(k) clearance from the FDA to market MDCT machines equipped with at least 16 detector rows, and at least two models of EBCT machines have been cleared by the FDA under Section 510(k). Intravenous iodinated contrast agents used for cardiac CTA have also received FDA approval.

Prospective studies with small sample sizes reflect that cardiac CTA is a promising noninvasive method for assessment of coronary stents, detection of in-stent restenosis and occlusion, and evaluating bypass patency. Studies with small sample sizes also conclude that the presence of myocardial hypoenhancement on cardiac CTA in acute chest pain patients has a high-positive predictive value and specificity, but only moderate sensitivity for presence of acute or healed MI. Additional studies conclude that the presence and size of early perfusion defects and late enhancement on cardiac CTA is closely related to follow-up segment myocardial dysfunction and myocardial functional recovery. Available studies recommend that further studies be conducted, to evaluate the clinical value of these preliminary findings in larger patient populations.

Current studies consist of patient populations with a high pretest probability of CAD. Patients providing suboptimal images are often excluded from calculations of test accuracy. Future studies will need to examine these tests in larger, less-selected populations representing the clinical settings in which they are actually expected to be used.

Appropriateness criteria for cardiac CT and cardiac MRI have been published in a report of the American College of Cardiology Foundation Quality Strategic Directions Committee Appropriateness Criteria Working Group, the American College of Radiology, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, American Society of Nuclear Cardiology, North American Society for Cardiac Imaging, Society for Cardiovascular Angiography and Interventions, and Society of Interventional Radiology. The working group acknowledges that clinical evidence is limited with respect to the clinical application of cardiac CTA in patient care algorithms and that there is little expert consensus. Although the appropriateness criteria are not specific guidelines, it is hoped that they may serve as an initial guide for this rapidly-evolving technology. The working group rates cardiac CT as an appropriate test and a reasonable approach for the indications listed as medically appropriate in this medical policy.

In 2008, a scientific statement entitled "Noninvasive Coronary Artery Imaging. Magnetic Resonance Angiography and Multidetector Computed Tomography Angiography," was published by the American Heart Association Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention, and the Councils on Clinical Cardiology and Cardiovascular Disease in the Young. The scientific statement recommends the adoption of criteria for cardiac CTA similar to the appropriateness criteria discussed above, and specifically recommends against screening asymptomatic individuals for coronary artery disease.

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In November 2014, FFR CT simulation software HeartFlow FFR CT (HeartFlow, Inc., Redwood City, CA) was cleared for marketing by the FDA through the de novo Section 510(k) process (class II, special controls; FDA product code: PJA). HeartFlow is a coronary physiologic simulation software used for the clinical qualitative and quantitative analysis of previously acquired CT digital imaging and communications in medicine (DICOM) data. The software provides a non-invasive method of estimating FFR using standard coronary CTA image data. In January 2016, the HeartFlow FFRCT v2.0 device was cleared through a subsequent Section 510(k) process.

In 2017, the National Institute for Health and Care Excellence (NICE) endorsed non-invasive FFR using coronary CTA (FFR-CT), stating, "The committee concluded that the evidence suggests that HeartFlow FFRCT is safe, has high diagnostic accuracy, and that its use may avoid the need for invasive investigations." For correct use, HeartFlow FFRCT requires access to 64-slice (or above) coronary CT angiography facilities. The American College of Cardiology CathPCI Registry (Messenger et al., 2017) also announced that it will allow FFRCT as an acceptable noninvasive method of documenting ischemia around the time of revascularization. Documentation of ischemia around the time of revascularization is important to the appropriate use criteria (AUC) for percutaneous coronary interventions (PCI).

Automated quantification and characterization of coronary atherosclerotic plaque is a service in which coronary computed tomographic angiography (CTA) data are analyzed using computerized algorithms to assess the extent and severity of coronary artery disease. Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent coronary computed tomography angiography (CCTA) for evaluation of coronary artery disease (CAD) or suspected CAD. This software is a post-processing tool that aids in determining treatment paths for patients suspected to have CAD. The Cleerly Coronary Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. There is a clinical trial entitled "Coronary CT Angiography Evaluation for Clinical Outcomes: An International Multicenter Registry (CONFIRM2)" that is sponsored by Cleerly, Inc. (Last updated February 27, 2020). This trial is designed to examine associations between CCTA imaging findings and clinical presentation and their ability to predict mortality and major adverse cardiac events in patients with chronic CAD. There is currently a lack of evidence that the use of the Cleerly Coronary Report would improve health outcomes of patients with CAD.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN)*

CPT Codes

Code	Description
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 left ventricular (LV) cardiac function, right ventricular (RV) structure and function and evaluation of vascular structures, if performed)

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Code	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
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
0623T (E/I)	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 (E/I)	data preparation and transmission
0625T (E/I)	computerized analysis of data from coronary computed tomographic angiography
0626T (E/I)	review of computerized analysis output to reconcile discordant data, interpretation and report

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HCPCS Codes

Code	Description
No specific code(s)	

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ICD10 Codes

Code	Description
Numerous codes	

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*Key Article

KEY WORDS

Cardiac CTA, Coronary artery CTA, calcium scoring.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA). Please refer to the following LCD website for Medicare members:

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33559&ver=28&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=2&bc=AAgAAAQBAAAA&=